EXHIBIT 32

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Bair Hugger Forced Air Warming Products Liability Litigation:	MDL No.: 15-2666 (JNE/FLN)
This Document Relates To: All Actions.	

VIDEOTAPED DEPOSITION OF WILLIAM R. JARVIS, M.D.
San Francisco, California
Tuesday, July 25, 2017

BY: HEIDI BELTON, CSR, RPR, CRR, CCRR, CLR
CSR LICENSE NO. 12885
JOB NO. 124789

July 25, 2017
9:00 a.m.

Videotaped deposition of WILLIAM R. JARVIS, M.D., held at One Market Plaza, Spear Tower, San Francisco, California, before Heidi Belton, a Certified Shorthand Reporter, Registered Professional Reporter, Certified Realtime Reporter, California Certified Realtime Reporter, Certified LiveNote Reporter, and NCRA Realtime Systems Administrator.

APPEARANCES:

For the Plaintiff:

LEVIN PAPANTONIO THOMAS MITCHELL RAFFERTY & PROCTOR
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Pensacola, Florida 32591

- AND -

PENDLEY, BAUDIN & COFFIN
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24110 Eden Street
Plaquemine, Louisiana 70765

- AND -

KENNEDY HODGES
By: Gabriel Assaad, Attorney at Law
4409 Montrose Boulevard
Houston, Texas 77006

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APPEARANCES (Continued):

For Defendants:

BLACKWELL BURKE
By: Corey Gordon, Attorney at Law
431 South Seventh Street
Minneapolis, Minnesota 55415

Also Present: Mordecai Boone, in-house counsel for 3M; Sean McGrath, videographer.

SAN FRANCISCO, CALIFORNIA
TUESDAY, JULY 25, 2017
9:00 a.m.

THE VIDEOGRAPHER: Good morning. This is the start of file number 1, Volume I of the videotaped deposition of Dr. William Jarvis, in the matter In re: Bair Hugger Forced Air Warming Products Liability Litigation in the United States District Court, District of Minnesota. MDL number 15-2666 (JNE/FLN).

This deposition is being held at 1 Market Plaza, Spear Tower, San Francisco, California on July 25, 2017, approximately 9:00 a.m. My name is Sean McGrath, from TSG Reporting, Incorporated and I'm a legal video specialist. The court reporter is Heidi Belton in association with TSG Reporting.

Would counsel please introduce yourselves, starting with the questioning attorney.

MR. C. GORDON: Corey Gordon, Blackwell Burke, on behalf of defendants.

MR. B. GORDON: Ben Gordon, on behalf of plaintiffs.

MR. COFFIN: Chris Coffin, Pendley, Baudin & Coffin, on behalf of plaintiffs.

MR. ASSAAD: Gabrielle Assaad, on behalf

of plaintiffs.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness and we can proceed.

(Whereupon, the witness, WILLIAM JARVIS, M.D., having been duly sworn, testified as follows:)

EXAMINATION

BY MR. C. GORDON:

Q. Good morning, Dr. Jarvis.

A. Good morning.

Q. We met briefly before. I'm Corey Gordon. I represent 3M in this litigation.

My understanding is you have been hired by the plaintiffs in the multi-district litigation involving Bair Hugger to offer an expert report; is that correct?

A. Correct.

(Exhibit 1 marked.)

BY MR. C. GORDON:

Q. I'd like to show you what I've marked as Jarvis Exhibit 1 and ask you to confirm that that is a copy of your expert report.

A. Looks like it.

Q. Okay. And you want to keep that in front of you because we'll refer back to that from time to time.

Now, this is -- it doesn't appear to be dated, but my understanding was that you would have signed this or -- that this became your final report somewhere around March 31, 2017; is that correct?

A. I believe that's correct.

Q. And on this Exhibit 1, starting at page -- well, I guess Attachment A. I'm sorry. That is your curriculum vitae; is that right?

A. Yes, sir.

Q. And is that -- is that essentially current? Is there anything that's changed since the end of March that -- of note?

A. No.

Q. Okay. And in addition there's a -- I'm looking for an Attachment B. That would be the list of lawsuits in which you've given expert testimony in the past four years. That's -- I think starts on page 32 at the end. Is that -- is it correct?

A. Yes.

Q. And again since March 31, 2017, any additions to this?

A. I believe there is [sic] two depositions.

Q. Do you remember the names of the cases or just generally what they were about?

A. Both were methicillin-resistant

Staphylococcus aureus infections.

Q. Were you offering expert opinions on behalf of the plaintiffs in those cases?

A. Yes.

Q. Were they product liability cases medical malpractice cases? How --

A. Medical malpractice.

MR. C. GORDON: We'll come back to your report. But I just want to get some housekeeping stuff out of the way.

(Exhibit 2 marked.)

BY MR. C. GORDON:

Q. Now the -- let me show you what's been marked as Exhibit 2 which is a set of invoices. I will just go through them. These were provided to me by Mr. Ben Gordon and Exhibit 2 should contain invoices from April 13, 2016; May 11, 2016; May 21, 2016; August 4, 2016; December 28, 2016; March 18, 2017; and March 23, 2017?

A. Yes, sir.

Q. Okay. Let's start with the beginning. Is -- would the April 13, 2016 be your -- the very first invoice for any work you've done in connection with the Bair Hugger litigation?

A. I believe that's correct.

Q. And this meeting or this invoice reflects a meeting in Atlanta, Georgia on April 11 and 12 of 2016; is that correct?

A. That's correct.

Q. So that was your very first touch point, if you will, with this litigation?

A. I'm not sure what you mean by "touch point."

Q. Obviously you had --

A. That was the first meeting --

Q. Yes --

A. -- but we had conversations before this.

Q. When you say "we," what -- with whom did you have conversations prior to April 11 and 12, 2016?

A. I couldn't tell you everyone, but certainly Mr. Gordon.

Q. Mr. Ben Gordon?

A. Yes.

MR. B. GORDON: Not Mr. Corey Gordon?

MR. C. GORDON: It's going to confuse the heck out of me if --

THE WITNESS: Mr. Ben Gordon.

MR. C. GORDON: The good-looking one. Let the record reflect the good looking one -- I don't

even know how to describe that sound.
MR. ASSAAD: I'm still confused. Can you --
MR. C. GORDON: I will stipulate.
MR. B. GORDON: You're muddying up the record.
MR. C. GORDON: I think we'll all stipulate Mr. Assaad.
Q. So was -- is it Mr. Ben Gordon and his law firm that initially retained you in this matter?
A. Correct.
Q. Do you have any retention agreements with any of the other plaintiffs' law firms that are involved in this litigation?
A. No.
Q. So at some point Mr. Ben Gordon or somebody from his law firm got in touch with you about this litigation; is that right?
A. Correct.
Q. Had you had any relationship with Mr. Ben Gordon or his law firm before you had done any work for them?
A. No.
Q. Do you know how they were -- how they found you or how they got to you?

MR. B. GORDON: Object to the -- I object to the extent it calls for privileged work product information. If there's anything that I told you about that, you don't have to say it.
THE WITNESS: I believe the contact was through another intermediary asking me if I would be interested in reviewing materials on the Bair Hugger. And I said yes. And then next was a conversation with Mr. Ben Gordon.
BY MR. C. GORDON:
Q. Was that intermediary a lawyer?
A. Actually, no.
Q. Okay. Then who was that?
A. I can't tell you. It was a woman in Washington DC. And I can't tell you her name.
Q. Was she a physician?
A. I believe she was an epidemiologist.
Q. Was she a government employee?
A. I don't believe so.
Q. Do you know what her involvement with the Bair Hugger litigation had been that caused her to be the intermediary?
A. No.
Q. What did she tell you about the matter in that first communication?

A. I am not absolutely sure. I believe we had a phone call and she just asked me if I would be willing to review materials related to the Bair Hugger.
Q. Had you had some relationship with this person before? Did she just contact you out of the blue?
A. I can't remember if -- she had contacted me I believe before that she did epidemiologic studies. And she contacted me because of my expertise in epidemiology and whether I would be interested in working with her.
Q. So after that, your next communication was with lawyers from -- or even Mr. Ben Gordon or lawyers within his firm?
A. Correct.
Q. The next invoice is from May 11, 2016. And that reflects a meeting in Atlanta, Georgia on May 9 through 10; is that right?
A. Correct.
Q. And I guess -- on your invoices you break it up into expenses and honorarium; is that right?
A. Correct.
Q. What do you mean by honorarium?
A. Other fees other than expenses.

Q. Why do you call them "honorariums" instead of "fees"?
A. No particular reason.
Q. I mean, do they go to some organization or something other than yourself?
A. No.
Q. They're paid to Jason and Jarvis Associates LLC; is that right?
A. Correct.
Q. And you're an owner of Jason and Jarvis Associates LLC?
A. Correct.
Q. Who is Jason?
A. Dr. Janine Jason, my wife.
Q. And the two of you are the sole owners of it?
A. Correct.
Q. And the next invoice is from May 21, 2016. And that reflects charges related to the Science Day meeting in Minneapolis on May 17 through the 18th; is that right?
MR. B. GORDON: I'm just for the record going to object to any inquiry concerning Science Day. I realize you're not going into the substance of it, but I just want to make sure I'm not waiving

it.
BY MR. C. GORDON:
Q. Right. I don't intend to get into the substance. But I just --
A. Correct.
Q. This is the bill related to your appearance at that Science Day; right?
A. Correct.
Q. And August -- the next one is August 4. And this would be a meeting in Portland, Oregon on July 24 through 25; is that right?
A. That's correct.
Q. And up to this point have all these meetings been just with lawyers or have there been other non- -- any other non-lawyers involved in the meetings?
A. I'm not sure I remember the attendees at all of the different meetings. But there certainly were non-lawyers at some of the meetings, yes.
Q. The last invoice in the pile that reflects a meeting in Los Angeles with Dr. Samet and the Bair Hugger team; right; is that right?
A. Correct.
Q. And we don't have to go through the other invoices just -- well, the August 4, 2016 reflects

another meeting in Portland but does not identify participants. And the December 2016 looks like it's all review of materials; is that right?
A. Correct.
Q. And the March 18 one is a meeting in Pensacola, Florida in February; right?
A. Corrects.
Q. So -- and then the final invoice that we have here in Exhibit 2 is from March 23 and reflects a meeting in LA with Dr. Samet and the Bair Hugger team on March 21, 2017; is that right?
A. Correct.
Q. And by the Bair Hugger team, is there anybody involved that you consider part of the Bair Hugger who was not a lawyer?
A. Again, I don't remember all the attendees but I think other than Dr. Samet's staff, that would probably be correct.
Q. Was there anybody else from Dr. Samet's staff that you recall?
A. Yes.
Q. Do you recall either who that person or people was or were?
A. I don't remember the person's name but I think it was an assistant.

Q. Male or female?
A. Female.
Q. Do you know if she was a physician?
A. I don't remember what her credentials were.
Q. Other than this meeting at -- with Dr. Samet and his assistant that's reflected in your invoice -- in your invoices, what other non-lawyers have participated in meetings that you recall? And if you don't remember names, if you can describe what you understood their background or their role to be.
A. I don't remember that I remember them all. Or even if -- who was at each of these specific meetings. Certainly one case one of the other experts was at the meeting. Obviously Science Day was the same.
Q. Which other expert was at a meeting that you remember?
A. One in Atlanta I believe Mr. Koenigsberg [sic] was there.
MR. B. GORDON: K-O-E-N-I-G-S-H-O-F-E-R. Koenigshofer.
BY MR. C. GORDON:
Q. One time?

A. I believe so.
Q. And besides Mr. Koenigshofer and yourself were there any other non-lawyers present at that one?
A. As I say, I don't remember specifically all the people who happened to be there. I don't believe there was.
Q. Did you have any meetings with Dr. Stonington?
A. No. In-person meeting? No.
Q. Did you have any phone calls with him?
A. I'm trying to remember. I may have had phone calls. Certainly had e-mail exchange.
Q. What were you exchanging e-mails with Dr. Stonington on?
A. I believe he had a couple of questions.
Q. He had questions for you?
A. Correct.
Q. Did you have any questions for him?
A. No.
Q. Do you remember what those questions were generally?
A. Not really, no.
Q. Were you able to answer them?
A. I sent a response back. You'd have to ask

him if it answered the question adequately or not.
Q. Did you have any communication with Mr. Buck?
A. I don't believe.
Q. How about Dr. Elghobashi? Did you have any communication with him?
A. No.
Q. How about Yadin David? Did you have any communications with him?
MR. B. GORDON: Yadin.
MR. ASSAAD: David.
MR. B. GORDON: Yadin/David.
BY MR. C. GORDON:
Q. I guess in America he goes by David.
A. No.
Q. Dr. David.
Okay. Anyone else that you can remember that you've had meetings with in connection with the Bair Hugger case who was not a lawyer?
A. Not that I recall.
Q. The invoices that we've marked as Exhibit 2, those reflect all your work on the Bair Hugger litigation through March 23, 2017; is that right?
A. Correct.

Q. And I assume that there has been or will be an invoice subsequent to the March 23, 2016 that would reflect the time you spent in preparing your expert report that was served on March 31, 2017?
A. Correct.
Q. So would it be correct to conclude from these invoices that you did all the writing of your report between March 23 and March 31, 2017; is that right?
A. I think probably some before that as well.
Q. And help me out here. Any -- you know -- there was one invoice where you reviewed some should materials back in December of 2016 but I -- but that's the only one I think that appears to be review of materials as opposed to meetings; am I right?
A. There -- I think there -- you could assume correctly that there would have been review of materials all along the way.
Q. Oh, okay. It's just not separately called out?
A. Correct.
Q. Now on that December 28, 2016, so long as we're on it, one of the things -- one of the items of your activities, it says, "Protocol Bair Hugger

study development and revisions," 13 hours there. What's that a reference to?
A. Developing a protocol for a study.
Q. What kind of study?
A. Assessing the Bair Hugger.
MR. B. GORDON: I'm going to object to the extent this calls for any of the substance of any consulting he did with us on what we believe is work product privilege information. Obviously he can disclose what he has disclosed. But in terms of the substance of any proposed study that didn't happen, we object to that as being protected by the work product privilege.
BY MR. C. GORDON:
Q. Have you conducted any studies in connection with the Bair Hugger?
A. No.
Q. Are you aware of anyone else other than Mr. Buck, one of the other plaintiff's experts who has done any study of the Bair Hugger as part of this litigation?
MR. B. GORDON: Yeah, if you came to know anything like that through counsel, then I'm instructing you not to answer. It would be privileged.

THE WITNESS: I guess it depends on how you word "study." You know, is review of material study? Or you mean actually conduct in vitro study of some sort?
BY MR. C. GORDON:
Q. Well, in vitro or in vivo, or I guess I want to limit it as an epidemiologist you would -- you could do a study reviewing, say, medical records; right?
MR. B. GORDON: Hang on just a second, Doctor.
I'm not sure what the question is, Corey.
BY MR. C. GORDON:
Q. Well, I just -- that was more of a response. I don't want to be very narrow. I'm just wondering if you are aware of any studies -- whether they're epidemiological, in vivo, in vitro, lab experiments, anything of that nature -- that were conducted with respect to the Bair Hugger of which you were apprised?
MR. B. GORDON: Before you answer, I'm going to object to the extent that anything you came to know -- if anything -- through counsel is protected by the work product privilege and instruct you not to answer. If you know of such studies

outside of any discussions with us, then you're free to answer.

THE WITNESS: Yeah, I would say excluding review of literature, actually conducting hands-on a study? No.

BY MR. C. GORDON:

Q. Okay. You haven't done any studies; that's what you're saying?

A. Or aware of other experts.

Q. Or aware of any. Okay.

And now Mr. Buck --

A. With the exception of Dr. Elghobashi obviously.

Q. Fair enough. I left that out. Unintentionally.

So you're aware that Mr. Buck did a study where he measured particles in an experimental setup; right?

A. Correct.

Q. And you're aware that Dr. Elghobashi commissioned a -- or directed a preparation of a computation fluid dynamics model? Are you aware of that?

A. Correct.

Q. And the protocol that you spent 13 hours

developing and revising, did that have anything to do with either Mr. Buck's experiments or Dr. Elghobashi's CFD model?

A. No.

Q. Mr. Buck measured particles in his report -- in his experiment that was reflected in his expert report. Were you familiar with that?

A. Correct.

Q. You read his report?

A. I did.

Q. Were you present when he did his experiments?

A. No.

Q. Do you know if he measured -- attempted to measure bacteria?

A. I'd have to go back and look at it. I don't believe he did.

Q. Would you agree that it would make -- from a scientific standpoint, that measuring bacteria is more relevant to issues relating to infection than measuring particles?

MR. B. GORDON: Object to the form. Assumes facts not in evidence.

THE WITNESS: Yeah, I guess I wouldn't use the word "more relevant." I think it adds other

information.

BY MR. C. GORDON:

Q. We'll get to that further.

So in coming to your opinions, did you rely on any experimental evidence, including anything that might have come out of your Bair Hugger study protocol that you developed over 13 hours that in any way informed your opinions?

A. I guess I'd ask you to reword that. I'm not sure --

Q. Okay.

A. -- what you're asking.

Q. You considered the Buck study. You considered the Elghobashi CFD; right?

A. Right.

Q. You developed a Bair Hugger study protocol that is apparently distinct from either Mr. Buck's or Dr. Elghobashi's works -- work; right?

A. Correct.

Q. Okay. And did anything conducted pursuant to or related to that Bair Hugger study protocol in any way inform your expert opinion?

MR. B. GORDON: Object to the form. Vague.

THE WITNESS: Well, obviously in

developing the protocol, that included extensive review of the medical literature as well. So it kind of goes with looking at all of the scientific data about the Bair Hugger.

BY MR. C. GORDON:

Q. Right. What I'm -- but what I'm asking about is if any study came out of the protocol that you developed and you were apprised of any results, did any of that inform -- if there was such a study, any kind of study conducted and if the results of it were shared with you, did that in any way inform your expert opinion?

A. No.

Q. Do you have an estimate as to how much time you would have expended in preparing your report that's not reflected in these invoices?

A. Not offhand.

Q. Just kind of eyeballing these invoices in Exhibit 2, it looks like they total about $90,000. Does that sound about right?

A. Probably in the ballpark, yeah.

Q. And subsequent to March 23, 2017, do you have any estimate as to how much additional time you've billed or -- either in time or in dollars for fees?

A. No.
Q. Do you have any estimate as to how much time you took in preparing your report?
A. Not offhand.
(Exhibit 3 marked.)
BY MR. C. GORDON:
Q. This morning your lawyer Mr. Gordon -- Mr. Ben Gordon -- handed me a document I've marked as Exhibit 3 entitled "Jarvis Additional Materials Reviewed." Do you see that?
A. Yes, sir.
Q. Is that -- is it something you prepared?
A. Yes.
Q. And just looking at the list of expert reports that start on the second page, it would appear that this includes at least some materials that did not exist at the time you did your initial report; is that right?
A. That would be correct.
Q. So when it refers to "Additional Materials Reviewed," when were these additional materials reviewed by you?
A. Some of these probably -- some of these definitely were reviewed before I drafted my report; they just weren't referenced in that report. And

you -- you were requesting all information in your subpoena that I looked at. So some of it is reflective of that and others are articles that I've found and/or read since I wrote that report.
Q. Okay. Well, obviously something that you hadn't reviewed prior to your report you couldn't have referenced. But if something is on Exhibit 3 that you reviewed prior to your report but didn't include in your references, what -- what should we take away from that, that you reviewed it but considered it not relevant to your report or --
MR. B. GORDON: Object to the form.
BY MR. C. GORDON:
Q. Tell me how -- tell me what the distinction you made between --
A. Well, there's --
Q. -- what you listed as references and what you listed as materials reviewed.
A. I would say the references in the report are peer-reviewed articles primarily that substantiate or describe or support various points that I'm making in the report. So if I read something that might have scientific interest and be relevant but I didn't refer to it in my report, then I wouldn't reference it.

Q. I want to ask you something about your report in -- that's Exhibit 1. On page 25 in the summary section you say, "In summary, having applied the methodological 'gold standard' approach which I used in my work for the CDC, I have come to the conclusion that" and then you go on to enumerate the details of your opinion; correct?
A. Correct.
Q. What is the methodological gold standard approach that you used in your work for the CDC that you applied to coming up with your expert report?
A. Well, some of that is described on page 3 of that report and involves investigation of outbreaks, and other parts are described in other parts of the report that refer to extensive critical review of the literature that is involved in development of guideline recommendations when I was at CDC.
Q. Okay. I'm a little confused here. On Exhibit -- excuse me. On page 3 of Exhibit 1, when you're talking about outbreak investigations that you did in the CDC, did you do anything similar to any outbreak investigations you did at the CDC in connection with the Bair Hugger litigation?
A. Well, some of it. Some of it talking

about a systematic review to do things.
Q. A systematic review of literature?
A. Correct.
Q. I understand that and I want to talk about it. I just want to -- again, I'm -- I just want to make sure you -- you didn't do any independent outbreak investigation --
MR. B. GORDON: Object to the form --
BY MR. C. GORDON:
Q. -- did you?
MR. B. GORDON: -- and counsel's characterization.
THE WITNESS: If you're talking about did I go on-site to a variety of hospitals, review medical records of parties that either had an exposure or did not have an exposure to the Bair Hugger, that would be correct.
BY MR. C. GORDON:
Q. I'm just trying to understand what -- I mean, when you were at the CDC, you did outbreak investigations; right? You talk about that on page 3.
A. Correct.
Q. And that -- and I think you were just saying now that when you refer to the CDC

methodological gold standard, that includes -- included outbreak investigations.

A. Correct. And that outbreak investigation includes an epidemiologic component and often a laboratory component. And in my review of the literature on the Bair Hugger, I included epidemiologic studies that included both laboratory as well as clinical studies.

Q. Your report, however, is based, I think, with the exception of reliance on Dr. Elghobashi's CFD. Correct me if I'm wrong. Otherwise it's -- it's completely based on your -- your systematic review of the medical literature --

MR. B. GORDON: Objection to form --

BY MR. C. GORDON:

Q. -- is that right?

MR. B. GORDON: -- asked and answered and described in his report. Mischaracterizes the evidence.

BY MR. C. GORDON:

Q. Yeah, I don't want to mischaracterize. I'm trying to understand what you're saying.

A. I would say that's correct, with the addition of it also includes my clinical training and epidemiologic experience. So it's a combination

of all of those.

Q. Right. But in terms of the methodological gold standard that you used at the CDC, did you do anything other than a systematic review of the literature?

A. In this case it was primarily a systematic review of the literature.

Q. You say "primarily," and that's why I'm -- I don't mean to pick nits here but did you do anything secondarily?

A. Well, for instance Dr. Elghobashi's study is not a peer-reviewed study in the literature --

Q. Okay.

A. -- so I looked at that.

Q. Anything else?

A. Mr. Buck's study is again not a peer-reviewed study. And there are one or two abstracts that I looked at as well. But it's primarily work that others have done primarily being peer-reviewed literature.

Q. Okay. And you reference Dr. Elghobashi's CFD in your report. Had you read Mr. Buck's report or at least knew of the results of his -- his experiments before you wrote your report?

A. I don't remember when I first saw that.

Q. Okay. And I'm -- I probably wasn't clear. Let me try to be clear here. I'm trying to focus in and learn everything you did and everything you considered in arriving at your opinion on or before March 31, 2017. Okay?

A. Okay.

Q. Anything you've done subsequently we'll talk about that separately, but this questioning I'm trying to focus on what -- what were the things you reviewed and considered that informed your expert opinion as of March 31, 2017. Okay?

A. Okay.

Q. Let's go back to your "Additional Materials Reviewed," Exhibit 3. And you said you think some of these you had -- or you -- I don't want to characterize that. Some of these materials reviewed that do not appear on your list of references were nonetheless things you would have read and considered prior to March 31, 2017; is that correct?

A. Correct.

Q. Are you able to go through and identify those that you would have read prior to March 31, 2017?

A. Some I would know; some I don't know. I'd

be guessing.

Q. Okay. Well, why don't you look at the list on Exhibit 3 and let's -- and I'm -- at this point I'm just focusing on articles. We'll get to depositions and expert reports later. But of the articles listed on Exhibit 3, can you identify any of those that, yes, you know for sure you read that prior to March 31, 2017?

A. As I say, some I could say definitively. Others would be a guess.

Q. Okay. Tell me the ones you know to be definitively.

A. Tuimia; Leaper; Lidwell, both.

Q. I think you did -- you've cited a couple of Lidwells in your references. Are these different?

A. They're different. I believe.

Q. Okay. Fair enough.

A. Kirksey.

(Reporter asks for repetition.)

Q. I'm sorry. What's --

A. Kirksey, K-I-R-K-S-E-Y.

Noble, Petty, Memarzadeh, Sharp. I believe Kuhme.

Q. Which one?

A. Kuhme.
Q. K-U-H-M-E?
A. Mm-hmm.
Sikka, Fletcher, Tande, Cram. I'm not sure about the anesthesiology paper. Brown.
Q. You're talking about Brown 2012; right?
A. Right.
The FDA website for heater coolers was both before and after. It's constantly changing.
The CDC update. The FDA safety communication.
The Parvizi study.
(Reporter asks for repetition.)
Parvizi, P-A-R-V-I-Z-I.
And Augustine 2014, I believe; not 2017.
Q. Okay.
A. The others I'd be guessing.
Q. Okay. And you said definitively, though, that you had not reviewed Augustine 2017 prior to your two reports; is that right?
A. I'm not sure on that. I don't remember the date. I think it was after, but I'm not sure.
Q. All right. We'll talk about that in a little bit. But of the ones that you can't definitively remember, are there any that you can

look at and say yeah, you know, I definitely had not seen that before March 31?
A. By name, no. I'd have to look at the paper and look at the title; it might jog my memory.
Q. Are there any subject matters reflected in any of these articles that you know that yeah, I hadn't looked at that prior to March 31, but I did look at -- look at that afterwards?
A. Oh, I think globally in terms of subject matters they probably all are in this same realm.
Q. Okay. How did you select the materials to review prior to rendering your opinion?
A. Combination of materials sent to me by counsel and many, many, many reviews of the literature both Google and PubMed.
Q. Do you recall what your search parameters or criteria were for your Google or PubMed searches?
A. Probably almost every combination you can think of. Forced air warmers, infections, surgical site infections -- prosthetic --
(Reporter asks for repetition.)
Forced air warmers, surgical site infections, prosthetic joint infections, Bair Hugger, normothermia, hypothermia. Crossed with -- surgical site infections with various organisms and

normothermia, hypothermia, Bair Hugger, forced air warmers.
Also looking at the various papers and looking at the references of those papers and going and reading those.
So as broad as I could possibly be of anything that was out there.
Q. Again, going back to your invoices on Exhibit 2. The only specific reference I see -- and I could be wrong, so please don't rely on me -- but the only reference I'm seeing specifically to review of any literature review was in the December 28, 2016 invoice. And that's really my question. Did I miss any? Are there any other places where you included in your invoice time for reviewing literature?
A. Well, for instance, on August 4 pre-meeting preparation --
Q. Okay.
A. -- may well include that.
Q. Well, and -- let's talk about that for a second because pre-meeting preparation appears on several of these. So I -- if -- let's -- let's address that.
Pre-meeting preparation would -- could

have included some of the literature review and the search -- searches that you did on Google and PubMed; is that right?
A. That's right.
MR. B. GORDON: Asked and answered.
BY MR. C. GORDON:
Q. So on April 13, 2016 there were -- you billed for two hours of pre-meeting preparation; right?
A. Correct.
Q. And on May 11, 2016 you billed for five hours of pre-meeting preparation; is that correct?
A. Correct.
Q. May 21, 2016, another five hours of pre-meeting preparation; is that right?
A. Correct.
Q. And August 4, 2016. That would be three hours of pre-meeting preparation; is that right?
A. Correct.
Q. December 28. That would be the one where you billed specifically two hours for literature review; right?
A. What date was that, please?
Q. December 28, 2016.
A. Correct. But protocol development and

revision does include that as well.
Q. Okay. So -- do you have an estimate as to what portion of the 13 hours you billed for protocol development and revision was actually spent in reviewing -- searching and reviewing literature on Google or PubMed?
A. Not offhand, no.
Q. Okay. And March 18, I don't see any pre-meeting prep; am I missing it?
A. No. There's none there.
Q. And March 23, again no -- no pre-meeting prep that I see; is that right?
A. Correct.
Q. Okay. So in terms of pre-meeting prep that -- if my math is correct, that would be a total of 15 hours; right?
A. That could be correct.
Q. And a total of -- well, 13 hours for the protocol development that involved -- may have involved some review of literature; right?
A. It did, yes.
Q. And two hours specifically for literature review; right?
A. Correct.
Q. So that's -- again, if my math is correct,

that's a total of 30 hours. Does that sound about right for the amount of time that you would have done research using all those search parameters that you just described on Google and PubMed?
A. You mean just doing the searches themselves or reading the materials that resulted from those searches?
Q. More of the latter. Reviewing -- well, both. Doing the searches and reading whatever it is you -- the searches generated.
A. Well, I would say that's accurate. Maybe even an underestimate, yeah.
Q. An underestimate?
A. It could be, yeah.
Q. Do you think that the $90,000 or so that you billed through March 23, 2017 is -- you underbilled? You didn't cover all your time?
MR. B. GORDON: Objection to form. Lack of foundation. Argumentative.
THE WITNESS: No. I think it's accurate.
BY MR. C. GORDON:
Q. Okay. Again, all I have are your invoices from March 23, 2017. So I'm just trying to understand.
Other than those -- the 30 total hours in

those three different categories, is there anything else that would have covered the time -- any amount of time that you spent in doing the Google and PubMed research and review of literature?
MR. B. GORDON: Objection to form. Vague.
THE WITNESS: No, I think that covers it.
BY MR. C. GORDON:
Q. Between March 23 and when you finalized your report on or about March 31, 2017, do you have an estimate as -- well, first of all, did you do any additional PubMed, Google search -- searches?
A. Yes. Probably did, yeah.
Q. Any estimate as to how much additional time you did?
A. Not offhand.
Q. So of the references you cited in Exhibit 1, what -- what percentage of those came as a result of your Google and PubMed searches versus some other means of gathering these?
MR. B. GORDON: Objection. Nitpicking again.
THE WITNESS: Yeah, I don't know that I could tell you exactly.
BY MR. C. GORDON:
Q. Some of the --

A. I would say the majority are from my searches.
Q. Okay. And would it be correct to say the -- most of the remainder would have come in materials provided to you by counsel?
A. Well, that -- that makes it some, yes.
Q. I don't want to presume that there was any other source.
So on Exhibit 3, the "Additional Materials Reviewed," just again those ones that you identified definitively as ones that you would have reviewed prior to issuing your report, can you -- do you know which ones of those came as a result of your independent search versus what you were provided by counsel?
A. Not offhand. But I'd say the majority are my searches.
MR. B. GORDON: I'll stipulate we provided him with depositions and the --
MR. C. GORDON: I'm just --
MR. B. GORDON: -- expert reports.
MR. C. GORDON: -- talking about the articles.
THE WITNESS: Yeah, I'm just talking about the articles too. I'd say the majority are from my

searches.
BY MR. C. GORDON:
Q. And how did -- what was your yardstick for determining whether the materials that you reviewed listed in Exhibit 3 but didn't include in your references, what was the yardstick by which you decided no, I'm not going to include that as a reference?
MR. B. GORDON: Objection to form. Vague.
THE WITNESS: Well, I'd say what's usually done is if you are writing a journal article or you're writing a -- at least when I'm writing a report if I'm substantiating a point or I'm particularly quoting or using materials from a publication, I would give that reference.
Many of these talk about -- many of these papers that I didn't reference are talking about organisms on the skin, dispersion intensive -- in an operating room, surgical site surveillance, et cetera, et cetera. And if I didn't quote from them in the report, I didn't reference them.
BY MR. C. GORDON:
Q. Because they didn't substantiate a point you were making; is that right?
A. Well, not necessarily. In many cases they

do substantiate the points that I'm making but they're not what I'm specifically quoting. I guess the problem is I could put in 250 references or a thousand references. But what value is that? If I'm referring to Avidan study and I'm quoting something from Avidan study, do I then put in 10 other studies that say the same thing? No.
Q. Is it your testimony that all the materials that you reviewed prior to March 31, 2017 but didn't include in your references are -- in no way question or contradict any of the points you've made?
A. I don't know that I would judge them specifically that way. They may have just been studies that I felt were very small studies or I had already made the point with another -- other reference.
Q. In describing the CDC methodological gold standard, you use the phrase "systematic review"; right?
A. Correct.
Q. Explain what you mean by "systematic review" in that context.
A. Well, an example of it would be in Dr. Wenzel's report where he seems to take all the

things that -- all of -- well, not all but many of the references he used is -- are to substantiate his point of view and ignores the huge body of the literature that doesn't agree with him.
Q. So what is a systematic review?
A. To me a systematic review is you try to look at every article that you can find. And I try to do that with my Google and PubMed searches that address the specific questions that we're trying to answer and not go in and pick two that I like that support my point of view and ignore 10 that refute it.
Q. So a systematic review would be not cherry-picking only those things that support a point you're trying to make; right?
A. Right.
MR. B. GORDON: Object to the characterization.
THE WITNESS: Unbiased review of the existing peer review literature.
BY MR. C. GORDON:
Q. So that methodological gold standard that you applied in coming to your opinion, that included trying to review all the relevant literature and not picking and choosing things based on whether they

supported or didn't support whatever opinions you were trying to make; is that right?
A. Tried to do that.
Q. And again going back to that methodological gold standard that you talked about with the CDC, the way the CDC came up with guidelines or did investigations was not to achieve a preconceived conclusion, but to see where the evidence led; right?
A. That's what we try to do.
Q. And that's what you tried to do in your report; right?
A. Correct.
Q. You didn't start out with a "I'm going to see what I can find to support this." You entered it with an open mind; right?
A. I tried to.
Q. And if you found something that called into question any of the conclusions that you were formulating at that point, you considered that and determined whether maybe you should step back and maybe think back whatever conclusion you were formulating; right?
A. Correct.
Q. Now, you've indicated that some of these

articles listed on Exhibit 3 you may have reviewed after your report; is that right?
A. Correct.
Q. Are there any articles that you reviewed after you issued your opinion that in any way made you think well, gee, if I had been aware of this before I issued my opinion, I would have maybe changed a conclusion or at least noted some disagreement?
A. I don't think so.
Q. One of the conclusions -- well, strike that.
Beginning on the bottom of page 14 of your report, Exhibit 1, you talk about airborne particulates and CFUs; is that right?
A. Yes.
Q. And you quote -- or you -- you cite to five different papers there; right?
A. Correct.
Q. And you say, "Cumulatively these studies show that airborne particle counts and microbial CFUs can be elevated near or at the operative incision site and that activities that increase the particle counts, microbial CFUs increase the risk of SSI." Correct?

A. Correct.
Q. Now, one of the things on your list of additional materials, Exhibit 3, is something identified as Cristina Exhibit 12? All right. Excuse me. 2012. Is that right?
A. Correct.
(Exhibit 4 marked.)
BY MR. C. GORDON:
Q. And I'm going to show you what I've marked as Exhibit 4 and ask you if this Exhibit 4 appears to be the Cristina 2012 article that you included in your "Additional Materials Reviewed," Exhibit 3.
MR. B. GORDON: I thought you didn't like Italy, Corey?
MR. C. GORDON: Who said that? I love Italy.
MR. B. GORDON: The memo you filed yesterday or the day before.
I'm just messing with you.
THE WITNESS: Correct.
BY MR. C. GORDON:
Q. So the -- and I'll certainly take time to look at it if you need to, but can you tell me if this is an article that you would have reviewed prior to or after you rendered your opinion?

A. I don't remember.
Q. Do you need to review to know basically what it says?
A. No. I think I remember some of it, yes.
Q. And would you agree that basically this was a study in orthopedic operating theaters and the authors concluded that particle counts did not correlate with bacterial colony-forming units?
MR. B. GORDON: Object to counsel's characterization. Document speaks for itself.
THE WITNESS: Repeat your question, please?
MR. C. GORDON: Could you read it back.
(Record read as follows:
"Q. And would you agree that basically this was a study in orthopedic operating theaters and the authors concluded that particle counts did not correlate with bacterial colony-forming units?")
MR. B. GORDON: Same objection.
THE WITNESS: Well, I think it was more limited than that in they do point out that neither fraction of their particulates -- and they only looked at two that is greater or equal to 0.5 microns or greater or equal to 5 microns -- that

that was not correlated with microbial load in the types of procedures they specifically examined.
As I recall it, procedures were short. I can't remember whether they had laminar flow or not. And they pointed out that they had a number of limitations in the study and it did not rule out the possibility of a correlation if they looked at other particle sizes.
BY MR. C. GORDON:
Q. So the fact they pointed out limitations, that was one reason you decided not to include it in what you considered or what you referenced in your report?
MR. B. GORDON: Object to form.
THE WITNESS: Well, I think it -- there were a number of other things that I think were odd about it as well. I can't remember if this is the one that found that -- let me look here.
As I say, I don't remember if I read this before or after. Another possibility also is, again, I used my experience and background with the CDC. And I have done a fair amount of work in Italy. And their operating rooms don't tend to be to the same standard, I would say, as an operating room in the United States.

But I think my primary concern was that they only looked at two specific rather than a broader range of particles. But they still found, you know, 35 colony-forming units per meter squared as a bacterial load in the operating room which is consistent with, again, finding airborne particles in the operating room. They just didn't find a correlation, but they were looking at too specific particle counts, not a wide range.

BY MR. C. GORDON:

Q. So on that basis you think that this would -- systematic review using the CDC gold standard methodology, this would not be something that would properly be considered in, say, coming up with a CDC guideline; is that right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, to be perfectly honest with you, in terms of the CDC guideline it wouldn't. Because right now the CDC guideline doesn't look at anything that's not a randomized control trial. I don't agree with it but that's what they do. So by definition CDC would not look at this at all.

(Reporter interruption.)

So from CDC's point of view, in terms of their -- for instance a surgical site guideline that

they have just recently updated, in that document they did not look at any study that was not a randomized control trial.

MR. C. GORDON: That's maybe an important distinction that we should talk about. Let me start off by marking Exhibit 5.

(Exhibit 5 marked.)

BY MR. C. GORDON:

Q. Could you tell me what that is, please.

A. This is a Centers for Disease Control and Prevention guideline for the prevention of surgical site infections 1999.

Q. And you were part of the CDC at that time; right?

A. That is correct.

Q. And you were part of a group of people who actually pulled together and prepared these guidelines; correct --

A. I --

Q. -- for this guideline?

A. I supervised this guideline.

Q. And so when you talk about the CDC methodological gold standard that you applied in coming up with your expert opinion in this case, would that be the same methodology that was employed

in coming up with the 1999 Exhibit 5?

A. To a large extent, yes.

Q. Are there any methodological differences?

A. Well, obviously here there's a -- what's called the Hospital Infection Control Practices Advisory Committee which is a federal advisory committee. So CDC -- a number of different groups at CDC have advisory committees. This was one for the hospital infections program at the time.

And when I look at review of the literature, I look at it personally and make a decision one way or the other. Whereas, in this case this group of people who were all supervised by me as part of my group did the literature search. But then this document after it was drafted was reviewed by the advisory committee. And they had some comments and suggestions on revisions. So that would be different than what I do specifically.

Q. I want to be a little bit more narrow in my question. In terms of deciding what literature to review and then what literature to reference in connection with the 1999 guideline, was that methodology any different than what you personally used in searching for, reviewing, and deciding what literature to reference in your opinion?

A. I'd say generally they would be the same. But if you get the specifics -- you know, this is obviously a very broad guideline. It tries to cover all components of surgical site infection prevention. It in fact is so broad that the recent CDC guideline revision did not undertake to do this broad a view but, rather, focused on -- I think it's either three or four specific surgical procedures. So we went very broad.

And I think one difference between what was done here and what I did is I tried to go very deep on a very narrow area: Normothermia, hypothermia, and the risk of infection. And basically methodologies to maintain normothermia and their impact.

So I'm going systematically very deep on a relatively narrow aspect. Whereas, this is trying to be comprehensive. But obviously if you're looking at such a broad range of different components, you may not go quite as deep.

Q. Again, my question may have been too broad and I -- see if I can clarify it.

A few moments ago you said that -- and the record is what it is; I'm not trying to put words in your mouth -- but that the CDC now will only look at

randomized control trials; right?
A. That's correct.
Q. Okay.
A. Certainly now. That was not this (indicating).
Q. And that's my point. Certainly in Exhibit 5 in the development of the -- this guideline, you and your colleagues looked at a lot of different medical literature beyond randomized control trials; right?
A. Contract.
Q. And all their -- their 497 references in Exhibit 5; right?
A. That's correct.
Q. And certainly those include some medical literature that was not based on randomized control trials; right?
A. Correct.
Q. And so the systematic review that you and your colleagues did for the 1999 surgical site infection guidelines, you're saying that's a different systematic review methodological gold standard than the CDC currently uses; is that right?
MR. B. GORDON: Object to form.
THE WITNESS: Well, the CDC approach to

guideline development has changed in a large number of ways over the years.
At the time this guideline was written, CDC staff did all of the review and all the drafting of the guideline and then the advisory committee then reviewed and gave their comments and suggestions, potential additions, et cetera. That has changed dramatically.
And now CDC basically farms out the guideline development. This guideline took us two years. It's very resource-intensive, personnel-intensive. And management in the division decided that that was overburdensome.
And so now the guideline development process is very different with outside -- basically contractors doing it. And then it's brought back into the advisory committee and the division and reviewed and revised.
So the whole process of how it's done and the literature upon which the guideline is based has kind of evolved and changed over the years.
BY MR. C. GORDON:
Q. I'd like to focus on the literature aspect of it, not the subcontracting and how -- how things developed.

Has the CDC changed its requirements for what literature can be considered in developing guidelines from the time you developed the 1999 guideline?
A. I would say that the literature that is used in the development of the guideline varies by guideline. For instance, the hand hygiene guideline was developed in 2002. And someday -- since it's -- what? -- 15 years old now, that guideline will be revised. If they limit themselves to randomized control trials, which they did with the surgical site update, there will be no guideline. Because there's not a single randomized control trial. So the inclusion criteria for the guideline changes by guideline.
Q. Where does one -- where would one find the inclusion criteria for the CDC's surgical site infection guidelines?
A. I would think it would be in -- I don't know that they ever actually enumerate specifically on the inclusion criteria. I think now the CDC guidelines tend to have huge appendices that give kind of an algorithm for how they went about their review and what article -- well, at least in terms of how many articles are included, how many

excluded, that type of thing.
MR. C. GORDON: Well, let's see if you can help me out here. I'm going to show you Exhibit 6.
(Exhibit 6 marked.)
BY MR. C. GORDON:
Q. And can you identify what Exhibit 6 is?
A. I believe this is the updated guideline that I mentioned that's much more limited, much more focused.
Q. And on the -- this would be the 2017 surgical site -- surgical site infection guideline update; right?
A. Correct.
Q. Okay. And there's -- under "Evidence Review," it refers to "A modified Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach." Do you see that?
A. Where are you reading that?
Q. Under the -- very first page, under "Evidence Review."
A. Correct.
Q. Do you have any idea what the -- what that "Grading of Recommendations, Assessment, Development, and Evaluation" concept is?
A. Yes.

Q. What is it?
A. This was proposed probably 15 years ago perhaps. And it's a grading of published peer-reviewed study articles with the highest grade being given to randomized control trial, systematic reviews and metanalyses. And -- I can't go into all of the details of it, but it talks about the design of the study, potential biases in the study, that type of thing.
And -- so this is where I mention that they have become much more focused on randomized control trials and looking at before/after studies, case control, cohort, other epidemiologic studies.
(Reporter asks for repetition.)
Case control or cohort studies or other types of epidemiologic studies.
So, for instance, in this guideline I believe it says that for antibiotic prophylaxis to dosing for obese patients, even though there is excellent pharmacologic data to show that if you're morbidly obese or obese you need a higher dose of the prophylactic antibody -- antibiotic in this they give it an unresolved issue because there's not a randomized control trial actually done in patients showing that. Makes no sense, but that's what

they've decided to do.
Q. I'm a little confused. Did -- under the GRADE approach, epidemiologic studies that are not randomized control studies can be considered as evidence?
A. Well, the GRADE -- I'm not that familiar with the grading. But I think the GRADE system first gives a grade for different types of studies. So you have randomized control trials, metanalysis, systematic reviews, case control, cohort studies, all the different types of epidemiologic studies and then grades them from highest to lowest. And then within those they talk about a variety of factors: Power, intrinsic biases, other types of biases that might be. And so they come up with ultimate score for various types of publications. So when they do their review, they then put each of these papers into little boxes. And at least from what I understand the decision was made on this specific guideline to only include randomized control trials and systematic reviews and metanalyses.
Q. So no epidemiologic data was included?
A. Well --
MR. B. GORDON: Object to form.
BY MR. C. GORDON:

Q. As you understand it.
MR. B. GORDON: Misstates testimony.
THE WITNESS: That would be epidemiologic data. But other types of epidemiologic data would be excluded.
BY MR. C. GORDON:
Q. Is it your understanding it would have excluded any cohort studies; is that right?
A. Correct. But they were not randomized control. Yup.
Q. Or case control studies?
A. Correct.
And it's just one approach. If you look at the Society for Healthcare Epidemiology of America that put out a compendium of recommendations or if you look at the Association for Professionals in Infection Control or if you look in fact at surgical societies, they don't take that approach. So there are various approaches to development of guidelines.
MR. C. GORDON: Let me show you Exhibit 7.
(Exhibit 7 marked.)
BY MR. C. GORDON:
Q. And my understanding is that Exhibit 7 is additional material that has been published by the

CDC online as the supporting documentations supporting backup for Exhibit 6; correct?
A. Basically a supplement, yes.
Q. Have you seen Exhibit 7 before? Either online or in hard copy?
A. Yes.
Q. And in connection with rendering your opinion here, did you have occasion to consult any of the supplementary online content in Exhibit 7?
A. Yes.
Q. When did you do that?
A. The specific online supplement material came out about the same time this guideline was published. But there was drafts of that guideline a number of -- not even months -- it may have been a year before. So I have reviewed the draft guideline and written public -- there's a public comment period and -- written comments about the guideline. That was probably a year or two ago. I don't remember. I don't believe all of this material was available at that specific time. This came out about the same time the guideline came out.
Q. Okay. And I want to direct your attention to page 7 of Exhibit 7. Under section "3.2. Literature Search." And the second full paragraph

where it says "Initial searches were designed to identify systematic reviews (SRs) and randomized controlled trials (RCTs). SRs that included non-randomized trials and observational studies (OBs) were eligible for inclusion. Three factors influenced the decision to limit literature searches to RCTs and SRs." And then it goes on to describe the reasons.

But would -- is that consistent with your understanding of what the systematic review approach used by the CDC for the 2017 systematic review prevention guideline was?

A. Well, I would say that was the systematic review for this specific guideline --

Q. Yes --

A. -- not all.

Q. -- that's what I want to ask.

A. Not all guidelines that CDC does or all guidelines that this division does. As I say, it basically evolves with changes with the guideline.

The other factor that was interesting was that they also decided that they would end their review in December of 2011 even though this guideline was being written in 2017. So that meant any randomized controlled trials, systematic

reviews, or metanalyses that were published between December '11 and May of 2017 were ignored.

Q. Okay. So in terms of what literature was considered for the 2017 surgical site infection guideline, is it your understanding that the CDC limited that search to systematic reviews which may have included randomized trials -- non-randomized trials and observational trials and randomized control trials?

A. Can you read that back? That was kind of long.

(Record read as follows:

"Q. So in terms of what literature was considered for the 2017 surgical site studies [sic] guideline, is it your understanding that the CDC limited that search to systematic reviews which may have included randomized trials -- non-randomized trials and observational trials and randomized control trials?")

THE WITNESS: I'm going to need you to reword that because --

MR. C. GORDON: Yeah.

THE WITNESS: -- it doesn't make any sense.

MR. C. GORDON: That's fair.

Q. Earlier I thought you said that the CDC limited -- was limiting its systematic reviews, not only randomized control trials; right?

THE REPORTER: "Not only randomized control..."?

MR. C. GORDON: "Trials now; correct?"

THE WITNESS: Well, I said randomized control trials, systematic reviews, and metanalyses.

MR. C. GORDON: Oh, you did? Okay. I'm sorry if I misstated.

MR. B. GORDON: Several times.

BY MR. C. GORDON:

Q. So this is consistent then with what you're saying; randomized control trials, systematic reviews, and metanalyses?

A. Correct.

Q. That is different than what you did in coming up with the 1999 surgical site infection guidelines; right?

A. Correct. More limited.

Q. The current standard that the CDC applied for the 2017 surgical site infection guidelines was more limited?

A. Correct.

Q. So going back to your statement in your expert report that you applied the methodological gold standard -- CDC methodological gold standard, that would be the standard that you were employing in 1999 when you came up with the surgical site infection guideline; is that right?

A. More inclusive, yes, correct.

Q. Not the current 2017 guideline?

A. Correct.

Q. And are there any studies that directly address the issue of anything related to specifically Bair Hugger in surgical site infections that you relied on in your report that would have passed muster under the current CDC surgical site infection guideline standard?

A. Well, I guess it would depend on how you define "pass muster." That there would be --

Q. Any randomized control trials.

A. There would be one randomized control -- well, the answer to that is in prosthetic joint infections, the answer is no.

Q. Okay. How about a metanalysis or systematic review?

A. Well metanalyses and systematic reviews are often also just limited to randomized control

trials. And the answer to that would be no. But prosthetic joint infections, no. There are no data that I'm aware of documenting an efficacy or normothermia or the efficacy of Bair Hugger in preventing infections in prosthetic joint infections.

Q. My question is whether Bair Hugger causes or contributes to peri-prosthetic joint infections. Are there any randomized control trials that you're aware of?

A. That's what I just said.

MR. B. GORDON: Object to form.

BY MR. C. GORDON:

Q. No. You were talking about normothermia. I'm -- I'm -- my question's about -- the allegations in this lawsuit, you understand the plaintiffs are alleging that the Bair Hugger caused their peri-prosthetic joint infections; right?

A. Correct.

Q. And your opinion is basically yes, that's correct; right?

A. Correct.

Q. And my question is under the current standards employed by the CDC for the development of the 2017 surgical site infection guidelines limiting

to randomized control trials, metanalyses, and --

MR. B. GORDON: Systematic review.

BY MR. C. GORDON:

Q. -- systematic reviews, are there any -- let's start with the randomized control trials -- any randomized control trial upon which you relied for your conclusion that Bair Hugger causes surgical site infections?

And just to be clear. When I -- I'm going to -- I may slip and say "surgical site infections." When I'm talking specifically about the lawsuit or the Bair Hugger in this context, I'm really talking about the allegations of the plaintiffs relating to peri-prosthetic joint infections. Okay? I'll try to say PJI to be clear. But if I slip, you may want to call me on it.

Are you aware of any -- do you cite or rely on any randomized control trial that you contend demonstrates that the Bair Hugger causes PJIs?

A. There are no randomized control trials, systematic reviews, or metanalyses documenting either the efficacy of Bair Hugger and preventing any complications in prosthetic joint infection or in prosthetic joint surgery patients or any

randomized control trials, metanalyses, systematic reviews documenting complications associated with Bair Hugger and prosthetic joint infections. There are no randomized control trials in prosthetic joint infections involving Bair Hugger.

Q. Okay. So your answer would be there are -- there -- there is no evidence in the medical literature that would meet the current criteria for the CDC surgical site infection guidelines?

MR. B. GORDON: Objection to form; asked and answered. Misstates the witness' testimony.

THE WITNESS: I'd say again that this methodology and approach was specific to this guideline and for very specific procedures. So it was not a revision of the entire surgical site infection guideline from 1999. But there were no randomized control trials, as I say, showing efficacy or detriment of the Bair Hugger in terms of prosthetic joint infections.

BY MR. C. GORDON:

Q. I noticed on your list of "Additional Materials Reviewed" that you got Sikka 2014. Do you recall reading that?

A. Vaguely.

Q. Do you know if that was one you recall you

reviewed before or after your opinion?

A. I believe it was before.

Q. Do you recall if that was a systematic review of all the literature available on --

A. I'd have to --

Q. -- whether forced air warming increases the risk of PJIs?

A. I would have to look at it. It's been awhile.

MR. B. GORDON: Corey, when you get to a good point, it might be a good time to take a break in a bit. My bladder is getting there.

MR. C. GORDON: Sure.

THE WITNESS: So excuse me. Your question again was?

BY MR. C. GORDON:

Q. Is the Sikka paper a systematic review?

A. Well, he doesn't really say. He has -- he basically has no methodology here. He says, "The purpose of the present manuscript is to review the current literature on the use of patient warming devices in orthopedic surgery specifically to joint arthroplasty. It never says what he did, how he did it, where he found them, how he evaluated them or anything else.

Q. And those are, in your view, problems with any kind of a published article; right?
A. Well, it would be nice if he had a methodology. I'd like to see how he went about what he did, number one, how he evaluated them, other than his personal opinion.
I think the difference is that this -- this is a review. How systemic it is, I'd have to look at more carefully to assess that.
Q. Where in your report do you explain your methodology in how you selected articles other than your own personal opinion?
A. I don't have a section where I say how I did it.
Q. I guess now is your time. How did you do it?
A. Mine is not a peer-reviewed paper though which the editor should have asked for.
THE REPORTER: Which who should have asked for?
THE WITNESS: Editor of the journal.
How I did it is -- as I said before, I tried to do as systematic and broad a review using Google search and PubMed for -- and using all combinations that I can think of of Bair Hugger,

forced air warmers, normothermia, hypothermia, surgical site infections, prosthetic joint infections specific to total hip/total knee arthroplasty procedures, et cetera, et cetera, as broadly and as many times as I could.
Also, when I found articles, there's a little link underneath PubMed where it says similar articles, click on that. And also going through those, trying to be as comprehensive as I could possibly be.
BY MR. C. GORDON:
Q. But you excluded some articles; right?
A. I didn't exclude any articles. I may not have included them in my report, as I mentioned before. If I had a specific reference to data from a paper, I referenced that paper. So you could go look at it and say is Jarvis quoting that correctly or not.
Q. Well, let's talk specifically about the Cristina paper. You would agree, would you not, that the Cristina paper is not consistent with what you conclude on page 15.
MR. B. GORDON: Page 15 of his report?
BY MR. C. GORDON:
Q. Page 15 of your report, yes.

A. Page 15 of my report says, "Cumulatively, these studies" -- "these" referring back to 1, 2, 3, 4, 5 studies -- "that show that airborne particle counts and microbial CFUs can be elevated near or at the operative/incision site and that activities that increase the particle counts/microbial CFUs increase the risk of SSI." And that is true.
Q. You would agree with me that the Cristina paper would -- is not consistent with the other -- with -- well, certainly it's not consistent with the Stocks paper that you cite there; right?
MR. B. GORDON: Object to form. Mischaracterizes the evidence. The document speaks for itself and addresses Stocks specifically.
MR. C. GORDON: That wasn't a speaking objection, was it, Mr. Gordon?
THE WITNESS: Repeat your question again?
BY MR. C. GORDON:
Q. The Cristina paper that you reviewed and excluded for the reasons you've talked about earlier, that is -- has conclusions that are inconsistent with the conclusions that you cite from the Stocks paper; right?
MR. B. GORDON: Objection to form. Mischaracterizes the evidence.

THE WITNESS: It -- I would word it differently. I would say she came to different conclusions using a different methodology.
BY MR. C. GORDON:
Q. Okay. And those different conclusions using a different methodology, they differ from the conclusions that Stocks, et al., came to; correct?
A. Correct.
Q. And you cited and relied on Stocks on page 15; correct?
A. One of five studies that I --
Q. Right.
A. -- reference, yes.
Q. Well, do any of the other studies that you reference on page 15 address the issue of whether particle counts correlate with bacterial CFU counts?
A. Well, Anderssen looked at both particle counts and CFUs. Darouiche looked at CFUs. I can't remember offhand if he looked at particle counts or not.
Q. My question is very specific. Does Andersson say anything about correlating the number of particles with the number of bacterial CFUs?
A. Well, he was correlating more the CFU with the amount of traffic.

Q. I understand that. Does -- Anderssen doesn't say anything about or even attempt to determine whether there's a correlation between the number of particles and the number of CFUs; correct?
A. Correct.
Q. Neither does Darouiche; right? It doesn't correlate bacteria --
A. Right.
Q. -- and particles?
A. Correct.
Q. Nor does Lidwell or Edmonson; right?
A. Right.
Q. The only article --
THE REPORTER: "Nor does Lidwell..."
MR. C. GORDON: Lidwell.
THE WITNESS: Or Edmonson.
BY MR. C. GORDON:
Q. -- you cite for the proposition that the number of particles that you can counts correlates with the number of bacterial CFUs is the Stocks 2010 paper; right?
A. In the report, yes, correct.
Q. And the -- in the report?
A. In the report.
Q. "In the report." Sorry.

And that's contrary to the conclusions that Cristina came up with; right?
A. Right, using a different methodology.
Q. Right. And in your report you don't take -- you don't mention the fact that there are -- that there's at least one contrary study to Stocks; right?
MR. B. GORDON: Object --
THE WITNESS: Correct.
MR. B. GORDON: -- to the characterization.
THE WITNESS: Correct. But I also don't mention a number of other papers that show the same thing.
MR. B. GORDON: If you're going to ask him to characterize these studies, he may need to look at these studies, Cory.
MR. C. GORDON: I understand.
Q. Well, tell me what other studies -- you pulled out some notes apparently -- so what other studies support the conclusion that measuring particles is a valid surrogate for -- or it -- strike that.
Tell me what other articles you're -- you're referring to that support the conclusion that

the count of particles is correlated with a -- bacterial CFUs?
A. Seal and Clark --
MR. B. GORDON: Seal and Clark.
THE WITNESS: -- Stocks, Raval --
BY MR. C. GORDON:
Q. How do you spell --
A. -- Birgand.
Q. What was the -- Raval?
A. R-A-V-A-L. And Birgand, B-I-R-G-A-N-D.
Q. Okay. Anything else?
A. No.
Q. And when did you review those -- well, start with Seal and Clark. When did you review that one? Before or after you are wrote your report?
A. I couldn't tell you.
Q. How about Raval? When did you review that?
A. I believe that was after.
Q. How about Birgand?
A. I can't recall.
MR. C. GORDON: Mr. Gordon -- Mr. Ben Gordon needs a potty break. So we'll do that.
THE VIDEOGRAPHER: The time is 10:36 a.m. We're off the record.

(Recess taken from 10:36 a.m. to 10:57 a.m.)
THE VIDEOGRAPHER: This marks the beginning of Volume I, file 2 in the deposition of Dr. William Jarvis. The time is 10:57 a.m. We're on the record.
BY MR. C. GORDON:
Q. Dr. Jarvis, the Stocks study that you cite on page 15, that found a correlation between particles and CFUs, do you recall that paper?
A. Yes.
Q. Do you recall the size of the particles that the Stocks group found correlated with CFUs?
A. (Witness reviews document.)
Can you read that back.
(Record read as follows:
"Q. Do you recall the size of the particles that the Stocks group found correlated with CFUs?")
THE WITNESS: Well, first -- and, again, in comparing to the Cristina paper, they looked at particle diameters of a much wider range. So .3, less than .5 microns. .5 -- less than .5 or equal to 1. 1 to 3 microns. 3 to less than 5. And then 5 to 10 microns.
Now, the particle size that they at least

describe in terms of correlation is a 10-micron particle.
BY MR. C. GORDON:
Q. What about the others micron sizes? Do they find a correlation?
A. Well, it looks like the P value of greater or equal to 10 microns is .001. 5 to 9.99 microns is .015. And 3 to 4.9 is 0.56.
The smaller, 0.3 to .49 is .23. 0.5 to 0.99 is .24. And 1 to 2.9 is .47.
Q. So you would agree -- so below 5 microns there was no correlation between particles; is that --
A. Well, 3 --
MR. B. GORDON: Object to form.
THE WITNESS: 3 to 4.9 is 0.56 [sic]. That's pretty close.
(Reporter asks for repetition.)
THE WITNESS: 3 to 4.9 microns, P value is 0.056.
BY MR. C. GORDON:
Q. Oh, you said "0.56." 0.056?
A. Yes, sir.
Q. That's technically not statistically significant though; right?

A. Well, you have to look at the data and look at the distribution and look at the 95 percent confidence interval. And it's close.
THE REPORTER: "And look at the"?
THE WITNESS: 95 percent confidence interval.
So it's close, but it's not, according to this, statistically significant.
BY MR. C. GORDON:
Q. Okay. And certainly below 3 microns, there's no correlation whatsoever; right?
A. In this particular study, correct.
Q. That's the only study you cite for correlation between particles and bacteria; right?
A. Well, actually the Darouiche study does as well.
Q. How does Darouiche correlate the number of particles and the number of bacterias -- bacteria?
A. Let me see if I have it. If I don't I'll borrow yours, if you don't mind.
(Witness reviews document.)
Could you read the question back again.
(Record read as follows:
"Q. How does Darouiche correlate the number of particles and the number of

bacteria?")
THE WITNESS: Well, they looked at particle densities as particles per cubic meter and had several size thresholds: 0.3 microns, 0.5 microns, 1 micron, 5 microns and greater/equal to 10 microns. And then they have a Figure 5 which shows a total particulates per meter cubed versus CFU per meter cubed.
BY MR. C. GORDON:
Q. Was the purpose of the study to try and determine whether there was a correlation between particle size and CFUs?
A. Obviously that was one of the purposes of the study. There were multiple purposes of the study. The study was to look at particulates. It was also to look at CFUs. It was also to look at SSIs and primarily randomized control trials. And one of the only randomized control trials here --
(Reporter asks witness to slow down.)
One of the only randomized -- well, the only randomized control trial in these five studies, it was particularly looking at a device that would remove particulates, and presumably therefore CFUs as well, from the operative site and its impact on surgical site infection.

It showed that as they decreased particulates and as they decreased CFUs, they saw a significant reduction not in superficial incisional SSIs -- which you would think, according to Dr. Wenzel's study that you would see -- didn't see that. But what you did see was by removing the particles in the CFUs from the air over the surgical wound, that you would decrease deep surgical wound infections.
Q. The particles and the CFUs were being removed simultaneously; right?
A. Correct.
Q. By a device called a Nimbic system; right?
A. I don't remember the name of the device but basically an air-sucking device that would remove particles. And some of those particles have CFUs.
Q. By the way, did you know that Dr. Stocks was a shareholder in the company that makes the Nimbic system?
A. Dr. Stocks?
MR. B. GORDON: Object to form.
BY MR. C. GORDON:
Q. Yeah, Dr. Stocks.
MR. B. GORDON: Lacks foundation.

THE WITNESS: No. I'm not sure how that has any influence on anything, but fine.
BY MR. C. GORDON:
Q. Dr. -- so the Darouiche study using this localized air filtration system was filtering both particles and CFUs; right?
A. Correct.
Q. It wasn't independently assessing whether in the absence of this device where they're removing both simultaneously particles and CFUs existed and moved up or down as -- in any correlation. It's completely different than the way the Stocks paper tried to correlate bacteria and CFUs --
MR. B. GORDON: Object to the form of the question.
BY MR. C. GORDON:
Q. -- right?
A. I don't know that I would agree with that.
They're both looking at -- at the fact there are particulates in the air. And some of those particulates in the air are either bacteria or particulates carrying bacteria. And one of the questions that is raised by Stocks as well as Darouiche is could you just measure particulates? Because particulates are much easier to measure.

One of the reason why I refer to the Raval study is it is a realtime method for determining bacterial count. So it kind of moves to the next level.
But before you have that with something like polymerase chain reaction or another type of molecular diagnostic test that could be realtime, you -- if you were looking for bacteria, you have to do cultures. And that takes days. So you get an answer, you know, three days from now, four days from now.
So one of the advantages of measuring particulates is you can do that with a laser particulate counter immediately. So if there is a correlation which Stocks and in a randomized control trial Darouiche shows, then you can measure particulates and extrapolate or correlate that with colony-forming units or bacterial contamination.
Q. Okay. And just so we're clear, your interpretation of the Darouiche study is that it was specifically looking at the question of whether you could just measure particulates and thereby get an idea of how many bacteria would be present?
MR. B. GORDON: Object to form. Misstates the witness' testimony. Argumentative.
THE WITNESS: Yeah, as I said there were

multiple results in the paper. Obviously the results in the paper are what they decided to study. They wouldn't have a result in a paper if they didn't want to study it. So obviously showing a correlation as they do in Figure 5 between particulates and CFU was a part of the study. They obviously did those measurements for a reason.
BY MR. C. GORDON:
Q. Did Darouiche, et al. conclude that there was a correlation between particulates and CFUs? Not your interpretation of a diagram --
MR. B. GORDON: Objection --
BY MR. C. GORDON:
Q. -- did they conclude that?
MR. B. GORDON: -- argumentative.
THE WITNESS: Well, it's not my interpretation of the diagram. When you publish a paper you have results in that paper. And one of the parts of my systematic review is to look critically and evaluate all of the data in the paper, not just some of the data in the paper, and see if I agree with what they conclude.
Let me see what he says.
MR. B. GORDON: By the way, Corey, there's no accent on the u. His name is -- is it pronounced

"Dar-u-shay"?
MR. C. GORDON: I have no idea.
MR. B. GORDON: Okay. I thought maybe we left the accent on the U off.
MR. C. GORDON: "Da-roosh." I'm sorry.
MR. B. GORDON: I've been looking for a long time when I was pronouncing it. I thought maybe you put that in personally.
MR. C. GORDON: No.
MR. ASSAAD: Da-veed [phonetic], David (laughter).
MR. C. GORDON: Well --
MR. B. GORDON: I'm just curious.
MR. C. GORDON: -- "Da-veed" was not pronounced that way in Israel.
MR. ASSAAD: Or in France?
MR. C. GORDON: Hmm?
MR. ASSAAD: In France it would be "Da-veed."
MR. C. GORDON: No. Well --
MR. ASSAAD: It would be. It's a big world out there.
THE WITNESS: Well, since his -- his bottom-line outcome that he was mostly interested in was SSIs, most of his discussion -- virtually all of

his discussion really focuses on surgical site infections and the fact that there are CFU counts elevated at the surgical site, when there are more people in the room, when there's more activity. And that this device removes them and it removes SSIs.

So he doesn't really address the particle count correlation with CFUs. But obviously that figure is in the table -- in the paper showing a correlation.

(Exhibit 8 marked.)

BY MR. C. GORDON:

Q. Showing you Exhibit 8. Is this the Seal and Clark article you referred to earlier?

A. Yes.

Q. If you could turn to page 29 -- 229 of this under discussion. The second full paragraph, second sentence. "For the ultra-clean theatre the statistical analysis shows there is a significant relationship between particles in the size range 5.0-7.0 microns and the BCP counted." I think it's bacterial -- bacterial-containing particles -- bacteria-containing particles. Sorry.

MR. B. GORDON: Is there a question?

BY MR. C. GORDON:

Q. Did I read -- well, first of all, do you

see that, where I read?

A. I believe so.

Q. And then they go on to conclude, "This demonstrates that counts of particles in the size range 5.0 7.0 microns may well provide a valid alternative to BCP counts as an indication of bacterial contamination in the vicinity of the operating site" -- "operation site in the ultraclean theatre [as read]."

Did I read that correctly?

MR. B. GORDON: No. Objection. You left out the word "airborne."

BY MR. C. GORDON:

Q. "Airborne"?

MR. B. GORDON: You don't like that word, I know.

MR. C. GORDON: No, I'll read it again.

MR. B. GORDON: Please do.

MR. C. GORDON: I didn't mean to -- "This demon- --"

MR. B. GORDON: I know you don't like "airborne."

BY MR. C. GORDON:

Q. "This demonstrates that counts of particles in the size range 5.0-7.0 microns may well

provide a valid alternative to BCP counts as an indication of airborne bacterial contamination in the vicinity of the operation site in the ultraclean theatre."

Did I read that correctly?

A. I believe so.

Q. And if you jump to the bottom of the next paragraph, there's a sentence where they say, "Particles less than 3 microns and greater than 15 microns clearly corresponded with activity even when bacteria were not detected."

Did I read that correctly?

MR. B. GORDON: For the record I'm going to object to your -- to use your phrase -- cherry-picking sentences out of a study that he may need to review more context.

MR. C. GORDON: Sure.

Q. Did I read that sentence correctly?

A. I believe so. It took me a while to find it, but I think so.

Q. Then if you drop down to the -- towards the bottom of the next paragraph, it says, "Particle concentration levels measured at 0.5-3.0 microns and greater than 15 microns in the turbulently ventilated theatre showed less relation to activity

than those in the ultra-clean system."

And then they go on to say "Because of the background effect of non-bacteria-carrying particles, we cannot recommend this alternative for bacteria counting in turbulently ventilated conditions."

Did I read that correctly?

A. You read that correctly.

Q. So Seal and Cro- -- I almost said Seals & Croft -- Seal and Clark you would agree -- as did Stocks -- or -- yeah, Stocks -- looked at different-sized particles; right?

A. I'd have to see what particle size they looked at. They looked at 8 size ranges between 0.5 and 20 microns in Seal and Clark. So there's some overlap. It didn't look exactly the same.

Q. Right. But would you agree that both Stocks and Seal and Clark ultimately concluded that whether -- whether in general you could correlate particles and bacterial counts depended on the size of the particles?

MR. B. GORDON: Object to the characterization for the record.

THE WITNESS: I guess I'd say that they found that certain particle sizes correlated in the

specific studies that they did under the circumstances they did with the methodologies that they used to test.
BY MR. C. GORDON:
Q. And certain particle sizes didn't correlate; correct?
A. In those studies, correct.
Q. Right. And the ones that didn't correlate, in both studies were small particles; right?
A. Very small particles.
MR. B. GORDON: Object to form.
MR. C. GORDON: "Very small particles."
(Reporter asks for repetition.)
BY MR. C. GORDON:
Q. And the ones that they found didn't correlate were small particles?
A. No, it's not --
MR. B. GORDON: Objection; "very small."
BY MR. C. GORDON:
Q. (Addressing the reporter) And he said "very small particles."
A. Very small. So less than .5 microns.
Q. Less than .5 microns. Okay.
And -- well, where do you -- I'm sorry.

Where do you find either Stocks or Seal and Clark finding a correlation between .5 and 3 microns, say?
A. On page 229 of the third paragraph it says, "It has been shown previously in an ultraclean theatre that measurement of particles in the 0.5 to 5-micron range gave peaks that correlated with airborne bacteria during the description of the ultra-clean conditions with the arrival and removal of the patient."
And they reference themselves, Seal 1985.
Q. And you interpret the peaks as indicating that whenever you've got -- that they concluded that whenever you got these sized particles present, that that correlates with bacteria?
A. That's what they're saying. I'm not saying it; they're saying it.
Q. Okay. They also found that -- Seals [sic] and Clark also concluded that there's a background effect of non-bacteria-carrying particles in a turbulent- -- ventilated turbulently theatre and they don't recommend counting particles as a surrogate for bacteria; right?
MR. B. GORDON: Objection; asked and answered.
MR. ASSAAD: What page?

MR. B. GORDON: 229. That last sentence he read.
THE WITNESS: Well, they point out that samples in ultraclean system would be more sensitive to transient concentration levels produced by activity than that in a turbulent.
BY MR. C. GORDON:
Q. They specifically say that in a turbulent system they don't recommend using particle counting as a surrogate for bacteria; right?
MR. B. GORDON: Objection to form. Misstates the evidence.
THE WITNESS: Well, they say particle concentration levels measured at 0.5 to 3 microns and greater than 15 microns in the turbulent ventilated theatre showed less relation to activity than those in the ultraclean system. The use of multiple-point sampling rather than single-point sampling that they used might give more accurate and consistent results. So they're saying that perhaps a different methodology would be better in that situation.
BY MR. C. GORDON:
Q. And what's the next sentence?
A. And then because of the background effect

of non-bacteria-carrying particles, we cannot recommend this alternative for bacterial counting in turbulent ventilation conditions. But they haven't provided any data to support that statement for the alternative. If they're talking about alternative bacterial counting being -- rather than using single point, using multiple point they don't provide any data to support that.
Q. Okay. But this -- so Seal and Clark, that's another study now that you say supports your conclusion that whenever you've got particles, you can assume there are bacteria there?
MR. B. GORDON: Object to the form.
THE WITNESS: Well, that misstates what I've said. I said they are authors that have done a study that have shown a correlation between particulate counts and CFUs, which is true. What they say is that they -- that their findings were stronger in a non-turbulent setting than a turbulent air setting. But they found a correlation.
BY MR. C. GORDON:
Q. You can't point to a single study that demonstrated that the Bair Hugger increased bacterial CFUs in the vicinity of the surgical site; correct?

MR. B. GORDON: Objection to form. Misstates his testimony and the evidence. Asked and answered.

THE WITNESS: That the Bair Hugger increases particulates in the sterile field?

MR. C. GORDON: No, that's not what I asked, sir.

Read my question back, please. Maybe Mr. -- maybe both of you misheard it. I think I was rather precise.

(Record read as follows:

"Q. You can't point to a single study that demonstrated that the Bair Hugger increased bacterial CFUs in the vicinity of the surgical site; correct?")

MR. B. GORDON: Note the same objection, please.

THE WITNESS: I'm trying to think if I have seen a study that looked specifically at that. Certainly we've seen studies that show that the intake air is not sterile; that the exhaust -- the air coming out is contaminated; the cultures of both intake and outtake lines are often culture-positive; that the filter used is inadequate; and that air even comes around the filter and doesn't go through

the filter.

But specifically looking at CFU, I know there are a number of studies looking at increased particulate counts; I don't think any of them specifically looked at CFUs.

BY MR. C. GORDON:

Q. Are you aware of any studies that have looked at CFUs and found that there was no increase attributable to the Bair Hugger?

A. I'm trying to think. There may be a couple of very small studies -- like, you know, five patients -- that may have looked at that.

Q. And the -- the studies that you cite for the increase in particulate matter, how many patients did they involve?

A. I'd have to go back and look at the specific papers. There's two, three, four -- at least six of them. I can't remember offhand.

Q. Tell me -- tell me what you're counting as the six papers that show an increase in particle size.

MR. B. GORDON: Objection; form.

THE WITNESS: What I said is --

BY MR. C. GORDON:

Q. An increase in particle counts.

(Reporter asks for repetition.)

An increase in particle counts.

A. So studies that showed the Bair Hugger increases particle counts in the sterile field would include Leaper, McGovern, Lague [phonetic], Reed, Tsai --

MR. B. GORDON: T-S-A-I.

MR. C. GORDON: T-S-A-I.

THE WITNESS: And Albrecht.

MR. B. GORDON: A-L-B-R-E-C-H-T.

BY MR. C. GORDON:

Q. Putting aside the Tsai one for a second -- I'll ask you about that separately -- those other five, did they involve a single patient?

A. I'd have to go back and look at each of those specific studies to answer that. At least McGovern did.

Q. McGovern involved patients?

A. Well, there were multiple parts to his paper.

Q. I'm talking about studies that showed -- that you're relying on for the notion that Bair Hugger increases particles at the surgical site.

MR. B. GORDON: Objection to form. That's what you should have asked.

THE WITNESS: Well, what I --

(Reporter asks for repetition.)

MR. B. GORDON: Then that's what you should have asked.

MR. C. GORDON: That is what I asked. That's exactly what I asked.

THE WITNESS: No, you said Bair Hugger increased particle counts.

BY MR. C. GORDON:

Q. Following on the heels of my -- well, okay.

Fine. Do any of those --

A. And all of those --

Q. -- do any of the studies that show an increase in particle counts anywhere involve patients?

A. Well, as I say, McGovern had multiple components to a study. And I would have to look at the others.

(Mr. Boone joined proceedings.)

Q. Okay. And do you recall as you sit here right now what McGovern component -- first of all, do you recall how McGovern came to the conclusion that Bair Hugger increased particles?

A. I believe it was the bubble study.

Q. Yeah. Okay.
(Reporter asks for repetition.)
Q. The bubble study.
A. Bubble.
Q. Did the bubble study involve a single patient?
A. No.
Q. Okay. So did any of those studies involve a single patient --
MR. B. GORDON: Objection; asked and answered.
BY MR. C. GORDON:
Q. -- those five studies?
A. Well, as I said, I'd have to go look at these each of those studies specifically to answer that question.
Q. You're not sure -- right? -- as you sit here?
A. No, I'd have to look at the papers.
Q. So if I were to tell you that not a single one of them involved so much as a single patient, you're -- you would say that you're not -- that that's not consistent with what you're recalling; you'd have to go back and check?
MR. B. GORDON: Objection; argumentative.

Asked and answered.
THE WITNESS: Well, I don't know that I would word it that way. I'd like to look at those papers and confirm that, number one.
And, number two, the fact that they show that increased particulates occurred with or without a patient -- you know, we're talking about the Bair Hugger. Does a Bair Hugger produce particles that end up over the operative field. If you have a patient there, obviously you have an increased risk of an infection.
BY MR. C. GORDON:
Q. When I asked you about studies that show that the Bair Hugger -- that looked at the number of bacteria that might be deposited at the surgical site when the Bair Hugger was used, you said well, those studies were small; they involved only a few -- five patients or so.
MR. B. GORDON: Objection --
BY MR. C. GORDON:
Q. Do you remember that?
MR. B. GORDON: Objection to form.
THE WITNESS: I remember something like that, yes.
BY MR. C. GORDON:

Q. But it's okay for you to rely on studies that show increased particles with not a single patient; right?
MR. B. GORDON: Objection; form. Argumentative.
THE WITNESS: Well, you're looking at -- at something that's different. My point with the other was not that there's a patient or there's not a patient. My point was that the number of measurements being done was small.
If you're looking for CFUs and I put an agar plate out here and I leave it out there for a minute, probably not going to have anything on it. If I leave it out there for a day or if I do a hundred of them, I'm much more likely to detect some CFUs.
So it more had to do with the study design than how many patients were there.
BY MR. C. GORDON:
Q. So good study design, you would agree, would have agar plates and active sampling; right?
MR. B. GORDON: Objection to form.
THE WITNESS: Don't know how you're defining active sampling. If you mean active air sampling?

BY MR. C. GORDON:
Q. Active air sampling. Like with an Anderssen sampler?
A. That would be a good way to do it, yes.
Q. Okay. That's exactly how Cristina did it; right?
A. Well, she did it, yes, that way. But she also had an electronic scalpel going on at the time. And that's really when she saw her particle count increase.
Q. Are electronic scalpels used in orthopedic implant surgery?
A. Some probably use it. And they use it for a limited period of time, in contrast to the Bair Hugger that's on the entire time. So it's a very different situation.
Q. They -- and in joint implant surgery, do they use electric drills?
A. Usually, yes.
Q. How about saws?
A. Yes.
Q. How about diathermy equipment?
A. I'm not sure about that.
Q. Have you ever heard of something called a Bovie?

A. Yes.
Q. What is a Bovie?
A. Basically it's a way to cauterize tissue or vessels or blood.
Q. An electric cauterizing tool?
A. Correct.
Q. And you've never heard that referred to as a diathermy tool or --
A. No, I usually hear the word Bovie.
Q. Okay. Does -- and are Bovies routinely used during implant surgery?
A. Routinely they're not used consistently and constantly like a Bair Hugger. They are used intermittently like a zzt [phonetic] and stop. So it's probably -- total time that it's used is maybe less than 5 or 10 minutes in the entire procedure.
Q. Does the use of the Bovie generate bio-aerosols?
A. It probably depends on what you're putting the Bovie next to.
Q. Inside a patient.
A. It can.
Q. How about drills? Do they generate bio-aerosols when they are drilling into a patient?
A. They can.

Q. How about saws? Do they generate bio-aerosols when they're sawing into a patient?
A. Well, I guess for all of these I would ask you what you mean by bio-aerosols. Are they producing microorganisms that are going to cause an infection? That's very different than are they producing smoke.
Q. What does smoke consist of?
A. Particles.
Q. Well, isn't one of the premises of your opinion that particles equate to bacteria?
MR. B. GORDON: Objection to form. Misstates his evidence -- testimony.
THE WITNESS: I don't know I say they equate. They correlate with.
BY MR. C. GORDON:
Q. Okay. So --
A. You know, of all the particles, some proportion of those particles are carrying bacteria. They're not all carrying bacteria.
Q. Okay. So the particles that are being generated with the use of a Bovie or a drill or a saw, that's spewing out bacteria in your opinion right?
MR. B. GORDON: Objection to form.

THE WITNESS: No. I've actually done Medline searches on all of those. And there's no correlation between any of those and infection. Unlike the Bair Hugger.
BY MR. C. GORDON:
Q. Have you seen any studies that have looked at impact of use of those -- any of those types of devices on the health of the healthcare workers?
A. Well, we're not really talking about health of healthcare workers, are we? We're talking about infections in prosthetic joint patients. That's very different.
Q. And you've seen -- you're saying you've seen studies that have actually looked -- cor- -- you have attempted to determine whether use of a drill or a saw, or a Bovie increases surgical site infections?
MR. B. GORDON: Objection to form. Misstates what he said.
THE WITNESS: I've done Medline searches and Google searches with key words being Bovie, many of the other devices that you've talked about -- saws, drills, et cetera -- and surgical site infections. And for most of those, nothing comes up.

BY MR. C. GORDON:
Q. When you say --
A. And in my 17 years of investigating outbreaks at the CDC, many of which were surgical site infection outbreaks, not a single one was associated with a Bovie, scalpel, drill.
We're talking about the Bair Hugger. The Bair Hugger that's been shown to have bacterial contamination. The Bair Hugger that's been shown to release air that's contaminated. The Bair Hugger that's been shown to increase particle counts, and those particle counts correlate with CFUs. Some proportion of those particles are carrying bacteria.
I know of no data that I have found -- if you can find one and show it to me, I'd be happy to look at it. But I've done extensive Medline searches looking at saws, looking at drills, looking at Bovies. And I can tell you there is not a single publication that I could find where any of those were associated with any prosthetic joint infection.
Q. Okay. Did you find any studies where any of those things were associated with bacterial contamination?
A. I don't know that I looked at them specifically for bacterial contamination. Do you

mean intrinsic contamination, or do you mean extrinsic contamination? Because most, if not all of those devices, when they come into the operating room are sterilized. Unlike the Bair Hugger, which we know and 3M has acknowledged is contaminated, is not sterile.

Q. Your understanding is that the drills and the saws come into the operating room sterilized? The whole saw, the whole drill, the whole electrocautery unit?

A. The part that is having contact with the patient? Yes.

Q. What about the rest of the equipment that isn't having any contact with the patient?

A. Well, if it's not having contact with the patient, then it may or may not be.

Most drills are sterilized. Ethylene oxide sterilization.

Q. The whole drill?

A. The whole drill.

Q. The motor, the fan, every part of it?

A. In some cases, yes.

Q. In some cases, not yes?

MR. B. GORDON: Objection; form.

THE WITNESS: I'd have to look at

different operating rooms. And, you know, obviously we're talking about the United States. I'd say the majority of them are. They're either sterilized or they're covered.

BY MR. C. GORDON:

Q. And you've seen no studies that have examined whether bacterial contamination of electrocautery tips or drills or saws or anything like that correlated with infections found in implant patients?

A. I've not seen any such data.

MR. C. GORDON: Okay. And let me show you Exhibit 10.

(Exhibit 10 marked.)

BY MR. C. GORDON:

Q. This is a paper called "Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial," by Oguz, et al. 2017.

Have you ever seen this before?

A. Yes.

Q. When?

A. I could not tell you when.

Q. It -- I don't see it on your list of -- either your list of references in your opinion or

your list of "Additional Materials Reviewed." Did I miss it?

A. I may have missed it.

Q. When did -- so is it something you would have seen before you rendered your opinion in this case?

A. As I said I don't remember.

Q. How did it come to your attention?

A. I don't remember if it came in from the search. I don't remember.

Q. Do you remember reading a study that actually -- that measured bacteria at the surgical site comparing a Bair Hugger to a HotDog during actual orthopedic surgeries?

A. I do remember this one. This was looking at various short orthopedic procedures without an implant. I think there was one, one knee replacement. So it really is very different than prosthetic joint infections with total hip and total knee arthroscopy.

Q. So if the Bair Hugger is -- harbors all this bacteria and spews out all these particles and some portion of those particles -- you know, as demonstrated by a handful of studies measuring bubbles and smoke -- if it's doing all those things,

you're saying it won't do that in a surgery that's -- doesn't involve an implant?

MR. B. GORDON: Objection to form --

THE WITNESS: Well, I --

MR. B. GORDON: -- and theatrics.

(Reporter asks for repetition.)

MR. B. GORDON: Theatrics.

THE WITNESS: Well, I think the data are -- are unanimously agreed upon in the scientific community that the number of organisms needed to cause an infection with an implant is much, much, much less than that in a patient that does not have an implant.

Furthermore, many of the studies -- in contrast to Dr. Wenzel who doesn't believe duration of operation has any impact or the number of people in the operating room -- most studies show that in fact those do correlate with infection. And the longer the procedure, the more people in the room, and the presence of an implant increases the risk of infection.

MR. C. GORDON: Move to strike as nonresponsive.

Q. My question, sir, is whether given all the things that you say that the Bair Hugger does, is

there any reason that it wouldn't increase CFUs when used in some procedure other than an implant procedure?

A. Well, as I said, it may increase the particle counts and the CFUs in a non-implant procedure. But given that the number of organisms is so much lower, many studies show that you need 10 of the 3, 10 of the 5 organisms to cause an infection if you don't have an implant. Whereas, you can have as small as maybe even one organism. Certainly 10 organisms can cause an infection with an implant.

So you're talking about lot of difference in risk associated with an implant in a patient versus a non-implant. And these are all simple procedures that are virtually all less than an hour; surgery on a ligament and soft tissue. You know, they're not even deep. We're talking about implants where -- I thought we were going to be talking about prosthetic joint infections. This has nothing to do with prosthetic joint infection.

Q. Move to strike as nonresponsive.

Sir, does --

MR. B. GORDON: Objection. It's perfectly responsive; you just didn't like the answer.

BY MR. C. GORDON:

Q. Does this study demonstrate that when the Bair Hugger is used as opposed to the HotDog, that there are more bacteria entering the surgical site -- field? Is that your understanding of it?

MR. B. GORDON: Take your time to read the study and look at the data if you need to.

Object to the form of the question.

THE WITNESS: Well, actually, it says the type of patient warming system had no significant influence on bacterial counts.

BY MR. C. GORDON:

Q. So it's the exact opposite of what I just said; right? This study using real patients showed that when you use the Bair Hugger, it doesn't increase bacteria in the surgical field over using the HotDog?

MR. B. GORDON: Objection to the form.

BY MR. C. GORDON:

Q. Right?

MR. B. GORDON: Object to form.

THE WITNESS: Well, in using it in short, non-implant surgical procedures --

MR. B. GORDON: I think you want to look at -- is this the right paper? I want to make sure

this is paginated correctly. I'm sorry. It's paginated different from mine.

What was the question, Corey?

MR. C. GORDON: Have the court reporter read it back.

MR. B. GORDON: Do you mind reading it back? Just because he's -- let him finish reading that, I guess.

Corey, is this your highlighting?

MR. C. GORDON: If it is, let's substitute this out. Yeah, I believe it is.

THE WITNESS: What is the question?

(Record read as follows:

"Q. So it's the exact opposite of what I just said; right? This study using real patients showed that when you use the Bair Hugger, it doesn't increase bacteria in the surgical field over using the HotDog?")

MR. B. GORDON: I object to the form and that characterization of the outcome of the study.

THE WITNESS: Yeah, I guess in terms of infection they -- the authors point out that the surgery was minor; that there were no SSIs at all; and that the end- -- if you were really going to

look at SSIs as your endpoint, you would need a much larger study than this since infections are so rare. And they point out that a large randomized controlled study should be done, which was recommended to 3M years and years ago and they haven't done it.

MR. C. GORDON: Move to strike as nonresponsive.

Q. Sir, it's a simple yes or no --

MR. B. GORDON: It was responsive.

BY MR. C. GORDON:

Q. Does this study show --

(Reporter asks for repetition.)

MR. B. GORDON: Objection; it was responsive.

BY MR. C. GORDON:

Q. Does this study show that when the Bair Hugger is compared in a randomized trial head to head with a HotDog there is no difference in the number of bacteria that make it to the surgical site whether you're using the Bair Hugger or the HotDog?

MR. B. GORDON: Objection to counsel's characterization. It's argumentative. It's asked and answered. He can answer the question the way he sees fit.

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THE WITNESS: Well, what they say is, again, that the study is very limited. That they had no difference in growth. But their multi-variant analysis -- which is very limited since there are only 80 patients in this study and no surgical site infections -- that indicate that a longer duration of surgery increased bacterial count on plates 1 and 4 and the absence of laminar flow increased bacterial counts on plates 1 and 6 significantly. And that there was a trend that longer duration increased the bacterial counts.
BY MR. C. GORDON:
Q. Right. But no difference between the --
A. But there again it was very limited because there's only 40 patients in each group and there were no infections.
Q. Only 40 patients. And --
A. In each group.
Q. Right. So a total of 80 patients?
A. Correct. So if there was a 1 percent infection risk, you'd have .8.
Q. Great. I'm not asking about infections. I'm asking about bacteria. That study showed no difference in bacteria; right?
MR. B. GORDON: Objection to form. You're

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mischaracterizing the evidence. You're totally ignoring Table 2. Just --
MR. C. GORDON: Object to the form of the -- "object to the form."
Move to strike counsel's speaking objection. Stop it, Ben.
MR. B. GORDON: I missed -- I object --
MR. C. GORDON: Stop it, Ben.
MR. B. GORDON: -- you're mischaracterizing what he said.
(Reporter interruption.)
BY MR. C. GORDON:
Q. Obviously, Dr. Jarvis, Mr. Gordon wants you to look at Table 2.
MR. B. GORDON: You want to cherry-pick what you want him to --
MR. C. GORDON: No. Stop that.
MR. B. GORDON: -- answer.
(Reporter interruption.)
MR. C. GORDON: Stop your speaking objections.
MR. B. GORDON: I'm going to object --
MR. C. GORDON: That one -- that one, I'm sorry, is over the top. And if you're going to pull stuff like that, we're going to terminate and go to

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the court.
MR. B. GORDON: Corey, I'm trying to wait until you finish so -- in respect for the court reporter so she can take us both down.
If you're mischaracterizing the evidence, I'm going to object to it. The doctor can look at the report and answer the question the way he sees fit. But if you're characterizing it in a way that's unfair and unrepresentative of what's in the study, then I'm going to object to that.
MR. C. GORDON: You're more than welcome to object, but --
MR. B. GORDON: If you want to call the judge, you call her right now.
MR. C. GORDON: You're more than welcome to object. But saying "Figure 2" is of the most clear and egregious form of a speaking objection.
MR. B. GORDON: Because you continually ask a question that ignores that part of it because you want to cherry-pick just the part you like.
MR. C. GORDON: Then object that it mischaracterizes the evidence.
MR. B. GORDON: I object you're mischaracterizing Table 2. Because it's right there.

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MR. C. GORDON: I didn't characterize Table 2.
MR. B. GORDON: You characterized the evidence as --
MR. C. GORDON: I'm --
MR. B. GORDON: -- not being where it is and what it is.
MR. C. GORDON: I'm through arguing with you.
Q. You know what? Let's move on, Doctor. You -- I think you made it pretty clear what you think about the Oguz paper. And even though you saw the Oguz paper, you didn't list it as either one of your references or either even the additional materials you reviewed; right?
A. I must have missed it.
Q. "Must have missed it." Okay.
On a number of occasions you talk about Dr. Wenzel, your disagreements with Dr. Wenzel. You've had some disagreements with Dr. Wenzel going back many years; haven't you?
A. Well, we probably disagree on some things, yes.
Q. Well, you had a rather vigorous public disagreement a few years ago with Dr. Wenzel on

the -- MRSA screening; right?
MR. B. GORDON: Objection; argumentative. Calls for facts not in evidence.
(Exhibit 9 marked.)
BY MR. C. GORDON:
Q. I'm showing you Exhibit 9. It's a --
MR. B. GORDON: 9?
MR. C. GORDON: Yeah. I had skipped it earlier.
Q. Series of letters back and forth to the editor of JAMA. Your -- your letter appears, I think, on the second page. Does that jog your memory as to -- I can mark more if you want.
MR. B. GORDON: What?
THE WITNESS: I'm trying to figure out what this has to do with Dr. Wenzel. This was actually a letter to the Ed. for about a Harbarth paper from Switzerland. I don't see Dr. Wenzel's name anywhere here.
BY MR. C. GORDON:
Q. Well, I'm not going to take the time to find it.
You don't recall having any back and forth where you disagreed with Dr. Wenzel about MRSA screening and is- -- isolation and detection --

detection and isolation of --
A. Active --
Q. -- MRSA patients?
A. -- detection and isolation?
(Reporter asks for repetition.)
Q. Active detection and isolation?
A. Yes.
Q. And you and Dr. Wenzel had different viewpoints; right?
A. Well, we used to have the same viewpoint and then he changed his viewpoint.
Q. Okay. And what was his -- what was the viewpoint that you shared at one point?
A. When he was at University of Virginia, he was one of the first in infection control to begin an active program of active detection and isolation of MRSA patients. He showed at University of Virginia a significant reduction in MRSA infections with that approach. Then about a decade later, he decided we shouldn't do that. And --
Q. Which part of that?
MR. B. GORDON: He's not finished.
THE WITNESS: And he has come up with this idea of horizontal versus vertical infection control. And I don't know if we want to go too much

time into that. But basically he would say vertical infection control would be like organism-specific. Like doing something for MRSA that might not have anything to do with C. difficile.
(Reporter asks for repetition.)
THE WITNESS: C. diff- -- Clostridium difficile. C-L-O-S-T-R-I-D-I-U-M. D-I-F-F-I-C-I-L-E.
MR. B. GORDON: Just C. difficile. Capital C. difficile.
THE WITNESS: That instead of doing that, he should do just horizontal things, like hand hygiene. A group of interventions that would prevent catheter-related bloodstream infection. But no longer identified colonized MRSA patients even though he knows and he has shown that colonized MRSA patients contaminate the environment and lead to transmission of MRSA just as well as infected patients.
So he changed his point of view despite the fact that he had previously published one of the first studies showing the efficacy of that approach.
BY MR. C. GORDON:
Q. You have consistently been an advocate for MRSA screening of all hospital patients; right?

A. No. I have been in favor of patient safety and reducing infections in all settings.
And with MRSA I have recommended that hospitals do a risk assessment to identify who their high-risk patients are and then do targeted surveillance of those high-risk patients to identify colonized and infected patients and place them in isolation. Because there are literally hundreds of published studies showing that that approach significantly reduces MRSA infections. Now, some hospitals have decided that it's just more feasible, practical for nursing personnel to screen everyone. Rather than just targeted patients.
But if you look at data, for instance, from the VA system, where they screen everyone, they have had a dramatic decrease in MRSA infections. If you look at some other hospital systems, the same thing has been shown. So to turn around now and say this approach does not work makes no sense.
Q. When you talk about MRSA screening how is the screening done?
A. Screening is done by doing swabs usually of the nose. You can do other body sites. But of the nose. And then there's a variety of approaches afterwards. You can either use culture; you could

use polymerase chain reaction; you could use selective media, not selective media.

(Reporter asks for repetition.)

MR. B. GORDON: Polymerase chain reaction, PCR.

THE WITNESS: PCR.

So you could use routine culture. You could use polymerase chain reaction or PCR. You could use selective or nonselective media.

So depending upon balancing how many are testing and how fast you want the result, cost issues, you can use one of those approaches.

BY MR. C. GORDON:

Q. You have been a consultant to one or more companies that manufacture products that are used for the -- for that detection; right?

A. I consult for companies that do and companies that don't.

Q. But you -- my question specifically relates to companies that do. Have you -- you have consulted for companies that have a financial interest in increased MRSA surveillance; right?

A. Well, I've consulted for companies that have made either polymerase chain reaction testing or types of culture media that could be used for

such testing.

Q. One of those is right near here; isn't it? Becton Dixon -- Dickinson?

A. I don't know if they're here, but BD is one of those companies. I haven't spoken in terms of MRSA for BD in probably five years.

Q. When you have written things about MRSA screening, you think it's -- you disclose your -- the fact that you've been a consultant to, among others, BD; right?

MR. B. GORDON: Objection to form. Argumentative.

THE WITNESS: It depends on what I'm writing, where I'm writing, what I'm saying. I have -- I would be hard-pressed to say that I've ever written an article where I've recommended a specific product. I talk generically about screening. How you screen is up to you to decide.

(Exhibit 11 marked.)

BY MR. C. GORDON:

Q. Show you what's been marked as Exhibit 11. This study you co-authored; correct?

A. Correct.

Q. And in this case you were comparing a couple of modalities for central line-associated

bloodstream intravenous connectors or something. I don't -- how do you explain what the device is you were --

A. This was looking at the incidence of central line-associated bloodstream infections associated with two different types or multiple types of needleless connectors.

Q. Needleless -- needleless connector. That's -- is that the device? Is that how you describe it?

A. Correct.

Q. Okay. And you were comparing one type of needleless connector to another; right?

A. Correct.

Q. And your study concluded that one type was better than the other; right?

A. Well, it actually wasn't a one-on-one. It was comparing one to a variety of others.

Q. The one that you were comparing to a variety of others was the zero fluid displacement needleless connector; right?

A. Correct.

Q. And that was made by RyMed Technologies; right?

A. Correct.

Q. Did you have any consulting arrangement with RyMed Technologies?

A. I did not.

Q. Let me show you what's been marked Exhibit 12.

Oh, by the way. Exhibit 11. This is published in a peer-reviewed journal; right?

A. It was, yes.

Q. So it went through the whole peer-reviewed process; right?

A. Correct.

Q. And that's important to you; isn't it? Peer-review?

A. Absolutely.

Q. And you -- earlier this morning you used that phrase several times. If a study is peer-reviewed, in your mind that -- that's some assurance that it's reliable; right?

MR. B. GORDON: Object to form. Object as --

THE WITNESS: No, I don't know. You know, I was an editor for a journal for -- that actually Dr. Wenzel initiated -- for over two years. I don't know what the review process is. I think the value of peer-reviewed is it's other scientists looking at

the data and making hopefully an objective evaluation of the merits of that paper.
BY MR. C. GORDON:
Q. You would agree with me that peer-reviewers can only review what they're presented with; right?
A. Absolutely.
Q. So if an author or authors mischaracterize the data or withhold certain data, peer-reviewers can't determine that based on what's presented; right?
MR. B. GORDON: Object to the form. Assumes facts not in evidence.
THE WITNESS: I guess that's somewhat true. Obviously if it's revealed, then they can. If it's not revealed, they can't.
MR. C. GORDON: Okay. So I'm going to show you Exhibit -- what's that? 12?
(Exhibit 12 marked.)
BY MR. C. GORDON:
Q. Have you seen Exhibit 12 before?
A. I know about it. I don't know that I've seen this specific piece of paper before.
Q. Okay. Well, you know that the article you co-authored that we marked as Exhibit 11 was

actually retracted by the journal; correct?
A. Correct.
Q. And originally it was retracted because there was a failure to disclose a conflict of interest; right?
A. By Dr. Chernecky.
Q. But once they -- the review committee at Georgia Regents University dug into it, they found not only that there was this failure to disclose this conflict of interest, but there were questions raised about the methods and data presented in the article; in particular, the consistency of the statistics over various study periods as well as the methods by which study sites were chosen. Right?
A. That's what it says, yes.
Q. And they concluded after this investigation, that the science was flawed; right?
A. Correct.
(Exhibit 13 marked.)
BY MR. C. GORDON:
Q. So now if one wants to look at the journal of this article which you co-authored, what they see is Exhibit 13; right?
A. I haven't pulled it up, but I would guess yes.

Q. Do you have any other articles you co-authored been retracted?
A. Not to my knowledge. And I was unaware of Dr. Chernecky's conflict of interest as well.
Q. Were you aware of the flawed science?
A. I don't know that --
MR. B. GORDON: Objection; argumentative.
THE WITNESS: Well, first of all, I don't know that I would agree with that. ICU Medical is the one that brought this up. And they've sued virtually every needleless connector manufacturer that I know of. And they didn't like the data. I don't know that I would agree with Georgia Regents. I think their concern was more the maintenance of the records than anything else. And the potential conflict of interest that Dr. Chernecky may have had. I looked at the data and I don't think it was flawed.
BY MR. C. GORDON:
Q. So you looked at the data and didn't think it was flawed. And that was -- the way it was presented to the peer reviewers, they apparently didn't think it was flawed because they signed off on it; right?
A. Correct.

Q. And after conflict of interest was raised, an interdisciplinary scientific review committee convened by senior leadership at Georgia Regents University, looked at it. And they concluded that there were questions about the methods and data and the consistency of the statistics. And they concluded -- this independent scientific review committee concluded that the science was flawed; right?
MR. B. GORDON: Objection; asked and answered.
THE WITNESS: Well, you read that before. Correct.
BY MR. C. GORDON:
Q. And you disagree with that?
MR. B. GORDON: Asked and answered.
THE WITNESS: Well, I didn't see their review. They obviously didn't share their review with me. I have no idea if the people at -- my guess is the people that did the review at Georgia Regents University know nothing about needleless connectors, know nothing about the science of this. I have no idea what the discussions were between Dr. Chernecky and that committee. So I can't really comment other than they made their review and made

their decision.
BY MR. C. GORDON:
Q. Did it concern you that a paper you -- you had your name on has -- is now retracted because an independent review committee concluded it was flawed science?
A. I wasn't happy about it, no.
Q. Well, did you do anything to find out what it was they thought was flawed about it?
A. No. What do you think, Georgia Regents University is going to change their action because I give them a call and ask them what's going on? That was really an evaluation of Dr. Chernecky, not me. So it was between she and her university.
Q. The investigation of the conflicts of interest involved Dr. Chernecky; right?
A. Correct.
Q. But the investigation of the statistics and the data analysis, stuff that they did after they started looking into conflicts of interest, that involved you too; right?
MR. B. GORDON: Objection; asked and answered.
THE WITNESS: Well, I've seen the data and I've done the statistics on the data and I don't

know what they found that they had problems with.
BY MR. C. GORDON:
Q. But you didn't try to find out?
A. No.
Q. You weren't curious?
A. As I say, I saw the data and did the analysis. So I -- I think I know how to do a T test, Fisher's Exact test, or chi-squared test.
(Reporter asks for repetition.)
T test, Fisher's Exact test. They're not very complicated. So I don't really think it was a statistical analysis that they were concerned about.
Q. But you never bothered to find out what they were concerned with?
A. I don't think they would have told me. But I didn't call them, if that's the question.
Q. All right. Well, did you call Dr. Chernecky ask her why this was retracted?
A. I can't remember if I had a conversation with her or not.
MR. C. GORDON: Why don't we take a lunch break.
MR. ASSAAD: Before we go on a break, I'd just like counsel for 3M to identify himself on the record so we have it on the transcript.

MR. BOONE: Sure.
I'm Mordecai Boone. M-O-R-D-E- --
(Reporter asks for repetition.)
M-O-R-D-E-C-A-I. Last name is Boone, B-O-O-N-E. And I'm secunded counsel at 3M Company.
THE VIDEOGRAPHER: The time is 12:06 p.m. We're off the record.
(Recess taken from 12:06 p.m. to 12:53 p.m.)
THE VIDEOGRAPHER: This marks the beginning of Volume I, file 3 in the deposition of Dr. William Jarvis. The time is 12:53 p.m. And we are on the record.
(Exhibit 14 marked.)
MR. C. GORDON: Dr. Jarvis, let me show you what I've marked as Exhibit 14.
Q. This is a document that your counsel handed me this morning. It looks like it's a printout of an e-mail?
A. Correct.
Q. Sent from you to Dr. Darouiche a couple of weeks ago, like three weeks ago?
A. Yeah, that's about right. Yup.
Q. Did you get a response?
A. No.
Q. You say in this e-mail to Dr. Derouiche,

"The other side's experts have been attacking and criticizing your paper."
Did I read that correctly?
A. Mm-hmm.
Q. Which experts have attacked and criticized Dr. Darouiche's paper?
A. I can't list them specifically. But I was told that.
Q. You were told it?
A. Mm-hmm.
Q. You didn't read it yourself?
A. No.
Q. Okay. Do you know -- well, were you told any of the defense experts were attacking or criticizing Darouiche paper?
MR. B. GORDON: I may have missed a question but I'm going to object to the extent it calls for information discussed between counsel. And, Dr. Jarvis, I caution you not to answer.
MR. C. GORDON: Yeah. If you're claiming there's some sort of privilege, he waived it when he told Dr. Darouiche that the other side's experts have been attacking and criticizing your paper.
MR. B. GORDON: You can take that position, but I'm not sure that would be -- I'm not

sure where he got the information. But if it came from me, I'm telling him not to answer and you can file a motion.
BY MR. C. GORDON:
Q. I want to know what your basis was for telling Dr. Darouiche that the other side's experts have been attacking and criticizing your paper.
MR. B. GORDON: And if your basis was from review of data, materials, analysis, then go ahead. If it's from me and I don't know if it is, but if it is, don't answer it.
THE WITNESS: No.
BY MR. C. GORDON:
Q. No what?
A. It's not from reading something.
Q. So is this -- this is based on something Mr. Ben Gordon told you; is that what your testimony is?
MR. ASSAAD: I instruct you not to answer anything other than that question. No substance of anything we talked about.
THE WITNESS: Yes.
BY MR. C. GORDON:
Q. Okay. What did Mr. Ben Gordon tell you was -- constituted attacking and criticizing

Dr. Darouiche's paper from the defense experts that you told -- that you sent this e-mail to Dr. Darouiche about?
MR. ASSAAD: Again, I'm going to object as that -- any conversation we had with Dr. Jarvis being protected by the attorney work product privilege. Instruct you not to answer.
BY MR. C. GORDON:
Q. You're going to follow his instruction, I assume?
A. Yes.
Q. Do you have any activities in connection with the CDC currently? Are you on any panels or advisory committees or anything like that?
A. No.
Q. National Institutes of Health? Are you on any committees there?
A. No.
Q. WHO?
A. I work with people with WHO but nothing formal.
Q. FDA?
A. Yes.
Q. What do you do for the FDA?
A. I'm chairman on one of their committees.

Q. What's -- which committee?
A. It's got a long name. "The General Hospital and Personal Use Panel."
Q. What is that panel?
A. It's an FDA committee that primarily focuses on medical devices, occasionally on methodologies, that FDA would use for assessing medical devices.
Q. All medical devices or is it some subset of medical devices?
A. I don't know that I can answer that. I'm -- we've discussed a number of different types of medical devices. Whether they have responsibility for all of them or some subset, I'm not sure.
Q. How long did you chair that committee?
(Reporter asks for repetition.)
How long have you been chair? I'm sorry. Was that -- if it's in your resume, I don't --
A. Yeah, it's in my resume.
Q. I'm sorry.
A. It's been years.
Q. Okay. That's fine. I just didn't -- if it's in your resume and it's been years, that's all I want to know.

A. Since 2007.
Q. Does that -- help me out here. What is the jurisdiction of the committee? Is it to review, you know, new device applications or 510(k)s or -- I'm just -- what -- what does the committee do?
A. Well, we're somewhat like a -- the HICPAC for CDC. Healthcare Infection Control Practices Advisory Committee. We're basically an advisory committee. So if the FDA has specific issues they want to address, they call me, e-mail me, arrange for a meeting, provide materials that the committee members look at. There may be formal presentations. We do not review 510(k) applications.
An example of it was that we've looked at, for instance, infusion pumps for insulin. Looked at methodologies for detecting Jakob Creutzfeldt agent. So it spans a wide variety of different activities but it's really directed by FDA.
Q. Does it meet regularly?
A. I would say it meets irregularly.
Q. Is it a committee that is called -- called upon when the FDA needs it as opposed to having regularly scheduled --
A. Exactly, yes.
Q. When was the last time you had a meeting?

A. Probably a year and a half ago.
Q. So it's not a frequent thing for you?
A. Correct.
Q. Has any -- have you addressed any issues relating to Bair Hugger in connection with that committee?
A. No.
Q. Have you raised anything in connection with the Bair Hugger through that committee?
A. No.
Q. Have you communicated with anybody at the FDA about what you've -- the opinions you've expressed in -- in your expert opinion here about the Bair Hugger?
A. Well, as you know I've signed a confidentiality agreement. So I would love for it to be raised -- released if you would like to do that. I'd be more than happy to. I've been -- tried to be very careful with who I've communicated with and what I've communicated about Bair Hugger until I'm allowed to.
Q. So I take it that you're saying no, you haven't communicated with anybody at the FDA?
MR. B. GORDON: Objection; asked and answered.

THE WITNESS: Correct.
BY MR. C. GORDON:
Q. How about the CDC; same thing?
A. Same thing.
Q. Any government regulatory agency? Have you communicated with anybody in connection with -- with any government body concerning your -- your -- the issues you raise with respect to the Bair Hugger?
A. No. Until the confidentiality agreement is lifted, I'm somewhat prohibited from doing so.
Q. One of the items on your "Additional Materials Reviewed," Exhibit 3, was -- or is -- Augustine 2017; is that right?
A. Correct.
(Exhibit 15 marked.)
BY MR. C. GORDON:
Q. Let me show you what I've marked as Exhibit 15 and ask you if that is the Augustine 2017 document you're referring to in your "Additional Materials Reviewed," Exhibit 3.
A. Yes.
Q. How did you first become aware of Exhibit 15?
A. I'm not sure if it came up in a search.

I'm not sure.
Q. So you don't know whether it was something you found on your own or somebody provided it to you? You don't know?
A. It may have been both. I don't remember.
Q. And how long ago do you recall first seeing it?
A. I think pretty shortly after it came out. I'm doing Medline searches all the time.
Q. Do you know when it came out?
A. I'm thinking it was January. But it doesn't say, so I don't remember.
Q. So you -- your recollection is that it was a while ago as opposed to in the last two, three, four or five weeks?
A. Yeah, I don't think it was -- as I say, it doesn't have a date on here --
Q. Okay. Your --
A. -- or a month anyway.
Q. Your expert report was January -- excuse me. Strike that. Your expert report was March 31, 2017. Do you know whether you had seen Exhibit 15 before or after that date?
A. I think it was probably after.
Q. Probably after?

A. I can't be absolutely sure but I think it was probably after.
Q. After March 31?
A. Yeah.
Q. But not in the last month? Not as recent as that?
A. Correct.
Q. Okay. And is there anything in Exhibit 15 that impacts your opinions at all?
A. Well, I think it's like the material I quoted in my report. You know, this is -- to me it's kind of putting pieces of a puzzle together and it's an additional piece of information that -- that supports the dangers of the Bair Hugger.
Q. So this is something you would consider a reference material that you would rely on to support your opinion?
A. I --
MR. B. GORDON: Object to the form. Characterization of reliance.
THE WITNESS: I think it's -- as I say, it's a piece of the puzzle like all the other references that I have in my report.
BY MR. C. GORDON:
Q. Okay. Well, if -- this isn't a reference

in your report so that's what I'm trying to understand. I mean, we went -- we talked about the Cristina study. That's also on your "Additional Materials Reviewed." But that's -- you know, you rejected that study as something you need to consider; right?

MR. B. GORDON: Object to the form. Mischaracterizes his testimony.

THE WITNESS: Right. I didn't say I rejected it. I read it and there were concerns I had in that particular study.

BY MR. C. GORDON:

Q. Did you have any concerns about Augustine's study, Exhibit 15?

A. Well, from reading it, it seemed like it was kind of following some of the same methodology as the Albrecht study. So, you know, seemed pretty straightforward.

Q. So unlike Cristina, you didn't have any concerns with Exhibit 15; is that right?

MR. B. GORDON: Object to the form. Argumentative.

THE WITNESS: Well, as I say, it provided data from three hospitals. Those hospitals collected the data. It seemed like Dr. Augustine

was pretty much as concatenating the information and had somebody that he paid, it sounds like, to do the statistics on it. So he was basically just kind of coordinating it.

BY MR. C. GORDON:

Q. Do you -- did you read Dr. Augustine's deposition?

A. I don't believe so.

Q. How did you -- how were the depositions you did read selected?

A. You would have to ask counsel that question.

Q. So you didn't ask for any specific witnesses?

A. Correct.

Q. And I think in your December billing statement you listed the -- several depositions that you had read. Hansen, Maharaj, Reed, Hannenberg, Albrecht, Bergstrom, Hamer, and Sessler.

A. Correct.

Q. And then on your "Additional Materials Reviewed," Exhibit 3, there's some additional depositions listed. So would those have been depositions that you read after your expert report? There's some overlap, I know that.

A. Yeah, some would be, some wouldn't be. As you say, there's some overlap. There's Albrecht, Reed, Bergstrom, Hamer, Sessler, Kurtz are all -- Hansen, Maharaj -- are all there. I think Lampotang was long time ago.

Q. Okay. McGovern?

A. McGovern also is --

Q. Go ahead.

A. I think the McGovern was probably done December-ish of last year.

Q. Yeah. It was actually early January of this year.

A. So definitely Stonington was after.

Q. It would have been --

A. Koenigshofer would be after.

(Reporter asks for repetition.)

Koenigshofer would be after.

Q. McGovern was originally scheduled for December but I got campylobacter.

(Reporter asks for repetition.)

MR. C. GORDON: Campylobacter.

MR. ASSAAD: Got sick. Bacteria. Got to wash those hands.

MR. C. GORDON: People that prepared my food needed to wash their hands.

MR. B. GORDON: British food. Sorry.

BY MR. C. GORDON:

Q. So you read McGovern before you wrote your report; is that your recollection?

A. I can't say for sure on that. I certainly read the paper. I can't say about the deposition.

Q. And when you -- well, okay. When you read the deposition -- when you refer to depositions, did you also get the exhibits that were part of the depositions or did you just get the transcript?

A. On that specific one I don't remember.

Q. On any of them.

A. I think on some I got exhibits; others I didn't.

Q. I don't see Legg on any of these lists. So you didn't read Dr. Legg's deposition?

A. I don't believe so.

Q. And it lists Albrecht. There's actually two volumes of Albrecht. Do you know if you read both of them?

A. I believe I've read one of the two.

Q. But not the second one?

A. No. I think I read the second one and not the first. I think.

Q. So I'm still trying to understand what

relevance Exhibit 15, the Augustine study, has to your opinions. It's now on your "Additional Materials Reviewed" list, but I don't know if that means using something that you consider a reliable piece of medical literature that you're going to base your opinions on or it's --

A. Well, I think it's --

MR. B. GORDON: Whoa, whoa, whoa, let him finish. Because I want to object.

Are you done, Corey?

BY MR. C. GORDON:

Q. Or --

Yeah.

Or it's something you're not taking into consideration.

MR. B. GORDON: Object to the form, counsel's characterization.

Go ahead.

THE WITNESS: Well, obviously since it's on my list everything on my list I take into consideration. I think that it is an additional piece of the puzzle, every one of these studies is further dated to support my belief that the Bair Hugger is a device that withdraws air that's not sterile, it's contaminated coming out of the device,

it increases particle counts over the operative field. And I think is causative for surgical site infections, particularly with patients with prosthetic joint infections.

And I think this is another piece of information or data from a peer-reviewed journal that supports that belief. And the three different hospitals using what looks like pretty similar methodologies found an increase in prosthetic joint infections when they were using the Bair Hugger.

BY MR. C. GORDON:

Q. So you believe that supports your opinion; right?

A. Correct.

Q. And you're relying on the scientific integrity of this Exhibit 15; right?

MR. B. GORDON: Object to the form. And the use of the word "relying."

THE WITNESS: Yeah, I don't know that I'm relying on it. It's a peer-reviewed journal that at least from looking at the data submission and the date of acceptance and publication and looking actually at the journal's website, that it's like any other peer-reviewed journal. So it's gone out for peer review.

BY MR. C. GORDON:

Q. Why did you look at the website?

A. Because I'm not familiar with that specific journal. I don't tend to read orthopedic papers. I had not heard of it before so I looked at it to see what it was all about.

Q. So did you see the fee that they charge for publishing papers?

A. I did see -- well, it's not as you describe. You don't pay them and then they publish your paper as they point out in the -- on the site, they don't require any money when you submit the paper. It's only when it's accepted for publication. And that's no different than the journal that Dr. Wenzel's an editor on. New England Journal charges page charges. Lancet charges page charges --

THE REPORTER: I'm sorry. "And that's something the"?

THE WITNESS: New England Journal of Medicine charges page charges. Lancet charges page charges. Every -- American Society for Microbiology Journal charges page charges. So that's a very common practice. And particularly journals that have online availability to virtually everyone.

They -- virtually all charge page charges. So I don't think that's anything unusual.

BY MR. C. GORDON:

Q. Does New England Journal require authors to identify two peer reviewers?

A. Actually, I've had quite a few articles published in the New England Journal and submitted in the New England Journal. And on every single one I've submitted we've given recommendations for reviewers. And I can tell you having been an editor of the journal, that is very helpful. Otherwise you're going into your database and just picking somebody at random. And I might pick you to do a review of a paper on which you know nothing. So it's actually much more useful if the authors can provide the names -- and preferably more than two -- of people who have expertise in the area.

Q. Move to strike as nonresponsive. Let me emphasize my -- the part of my question that I -- I -- you may not have heard.

Does the New England Journal require authors to submit two peer-re- -- names of two peer reviewers?

MR. B. GORDON: Objection to form. Asked and answered.

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THE WITNESS: Well, I think the answer to that I'm not aware of any journal that requires you to do that. But most journals are more than happy when you do do that.
BY MR. C. GORDON:
Q. Do you know Dr. Augustine?
A. Never met him.
Q. Have you ever talked to him?
A. Nope.
Q. Do you know that he's quoting your expert report in marketing materials?
A. No, I was not aware of that, no.
Q. Does that surprise you?
MR. B. GORDON: Objection; argumentative.
THE WITNESS: I'd have to see it. I don't know, you know, what he's saying.
BY MR. C. GORDON:
Q. Let's look at Exhibit 1, your expert report. And I'm going to ask some questions. Let's start on page 5. At the top of the page where you say -- where you emphasize that "None of these patient-specific characteristics causes the infection; the pathogen causes the infection." Do you see that?
A. Yes.

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Q. Well, that would be true of the Bair Hugger as well; right? The Bair Hugger itself even in your formulation doesn't cause the infection --
MR. B. GORDON: Object to the form.
BY MR. C. GORDON:
Q. -- it would be the pathogen; right?
MR. B. GORDON: Calls for a legal conclusion. Object to the form.
THE WITNESS: Well, it absolutely depends upon the pathogen. The difference is that the characteristics that we're talking about, most of the characteristics in terms of risk factors, you know, enhance the likelihood of infection giving contamination; whereas, in the case of the Bair Hugger, it's actually a source of the organisms.
BY MR. C. GORDON:
Q. So you're distinguishing between source and -- what -- how would you characterize patient-specific factors if they're not sources?
A. Risk factors. So there's risk factors enhance the likelihood that if contamination were occur [as said]. But if you're a diabetic, that doesn't increase the likelihood that you have a bug in your wound. Diabetes doesn't produce any bugs in your wound. Diabetes just makes it if you get a bug

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in your prosthetic device you have an increased risk of going on and developing an infection.
Q. Would you characterize that as a host immunity factor?
A. Absolutely it would be, sure.
Q. And would you agree that there are patient-specific risk factors that actually increase the bio-burden of bacteria that the patient brings to the table?
MR. B. GORDON: Object to the form.
THE WITNESS: You mean specifically on certain body sites or more likely have naso-colonization? Can you ask it a little bit --
BY MR. C. GORDON:
Q. Well, let's back it up a different way. On the next paragraph you say, "exogenous sources account for the SSIs"; right?
A. Correct.
Q. What's an exogenous source?
A. Exogenous source is a source outside of the patient.
Q. What's --
A. And then part of that is based upon my experience over 23 years at CDC. We -- I was in charge of the outbreak investigation group for 17

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years. We investigated more outbreaks than anyone on this planet. And of the surgical site infection outbreaks that we investigated, almost all of them were due to exogenous sources. There was one that was due to a patient source.
Q. What's the opposite of an exogenous source?
A. Endogenous.
Q. Okay. So my -- I guess my question is are there any patient-specific risk factors that increase the endogenous sources of bacteria?
A. I'm trying to think if there's any studies that have been done to really answer that question. There certainly have been studies that have looked at different patient populations to see who's colonized, who's not colonized, even some studies looking at the degree of colonization in one location to the other. But I don't know that they address your specific question.
Q. What years were you at the CDC?
A. 1980 to 2003.
Q. So by the time you supervised the preparation of the 1999 surgical site guidelines, Exhibit 5, you had already been at the CDC almost two decades; right?

A. 19. Well, I probably started at least two years before that. But, yeah, over 15 years.
Q. Okay. And going back to the sentence where -- in your report where you say, "Exogenous sources account for the majority of SSIs," you didn't actually cite any medical literature for that proposition, did you?
A. No.
Q. You just said -- that was based on your years of experience at the CDC; right?
A. That was based on the outbreaks that we investigated when I was at CDC, as well as scientific literature.
Q. Could you turn on Exhibit 5 to page 103. Direct your attention to the first full paragraph on that page. Could you read that first full sentence.
A. The first full sentence?
Q. Beginning with, "For most SSIs."
A. "For most SSIs, a source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera."
Q. And for that there's a citation; correct?
A. Correct. A study from 1968.
Q. The Altameier, Culbertson, and Hummel study?

A. No. Actually --
Q. Did I get that wrong?
A. Oh. 57. Yes, yes. Right. 1968, right.
Q. So the sentence in your 1999 CDC guideline says, "Most pathogens are endogenous." And in your report you say "most are exogenous." Right?
A. Right. And the --
Q. Did something happen in the last four years of your CDC tenure to make you change your mind about everything you learned in the first 19?
MR. B. GORDON: Objection to form. Mischaracterizes the evidence. And argumentative.
THE WITNESS: Well, couple of things. One is it talks about endogenous. And then it talks also about exogenous organisms as a source of SSI include surgical personnel; operating room environment; all tools, instruments, materials brought to the sterile field during the operation. So it doesn't exclude those.
But if you look at what happened between this guideline -- and, actually, it started a little bit before this guideline -- but a tremendous number of interventions have been applied to patients to reduce the endogenous flora and the importance of the endogenous flora. Most of the Center for

Medicare/Medicaid services or CMS -- what's called SCIP measures -- which is a surgical care improvement -- surgical infection prevention.
Activities were really focused at the endogenous rather than exogenous flora. So, for instance, improvement of prophylactic antibiotics, improvement in skin antisepsis by the use of chlorhexidine alcohol rather than povidone iodine.
(Reporter asks for repetition.)
"Chlorhexidine alcohol rather than povidone iodine."
Those activities were really aimed at the endogenous flora. So there's really a lot of activities on endogenous flora; not as many necessarily on the exogenous flora.
BY MR. C. GORDON:
Q. Okay. So as of 1999 you were satisfied that the state of the medical literature was such that you could say that the majority of SSIs were caused by endogenous flora; right?
A. Right. As endemic infections, yes.
Q. And that's changed in the last 18 years for the reasons you mentioned; right?
A. Correct.
Q. Are you aware of any medical journal,

textbook, anything in the last 18 years that has said what you say, which is that the majority of SSIs are caused by exogenous sources?
A. Well, certainly the Seminars journal that we gave you a copy of that gives a list of all the outbreaks that CDC did as well as the role of the environment. There's a number of papers in that that document the role of exogenous sources of infection.
Q. My question is very specific. You were satisfied in 1999 that the majority were caused by endogenous sources. And you actually cited one published paper for that. In the 18 years since the 1999 guidelines were published, has any medical journal or textbook published any kind of a conclusion -- study, metanalysis, anything -- that concludes that now things have shifted so such that the majority of SSIs are exogenous?
MR. B. GORDON: Object to form; asked and answered.
THE WITNESS: Well, I don't know that I've done a search for, you know, every -- it wouldn't -- Medline search wouldn't pick up books anyway. But I'm not sure I've seen a specific paper looking at that.

As I say, the Seminars journal that we gave you shows all the CDC outbreaks that we investigated and the surgical site outbreaks in particular. Of the 22, 20 of the 22 -- actually, 21 of the 22 are exogenous sources of infection. The reference that we gave here is 1968. So it probably was changing even at this time.

BY MR. C. GORDON:

Q. Is the CDC called in for -- every time there's a surgical site infection?

A. I doubt it. They'd be kind of busy if they were. No.

Q. In fact, the CDC is not called in for the overwhelming majority of surgical site infections that occur every day and throughout the country; right?

A. Absolutely. Or healthcare-associated infections in general. And they have to be very specific in what they investigate. And we try to pick outbreaks that would advance the field of infection control and not be redundant of something that's been shown 20 times.

Q. Okay. So if patients are experiencing common surgical site infections that arise from endogenous flora that have been studied many times

over the years, that would probably not be something that would result in a CDC outbreak investigation?

MR. B. GORDON: Object to form.

BY MR. C. GORDON:

Q. Right?

MR. B. GORDON: Lack of foundation. Calls for speculation.

THE WITNESS: Well and that's probably not true. It depends on the organism. For instance, like the heater-cooler investigation was a very unusual organism. Very similar to what we're dealing with here with Bair Hugger where it was a device that was used for decades and thought to be perfectly safe. That then only was recognized as being a cause of infection because Mycobacterium chimaera infections were occurring in cardiac surgery patients. And that was very unusual. So certainly if the heater coolers have been associated with Staph aureus infections it probably would have taken a lot longer before it would have been recognized.

BY MR. C. GORDON:

Q. And my question went to garden variety infections. Let's take Staph epidermidis. That's a pretty common surgical site infection; isn't it?

A. Correct.

Q. And probably everybody in this room has Staph epidermitis bacteria; right?

A. Correct.

Q. Some maybe more than others.

A. Possibly.

MR. ASSAAD: For the record Corey Gordon just looked directly right at Mr. Assaad, which is myself, talking about Staph epidermis.

MR. C. GORDON: Are you feeling guilty? Sorry.

MR. ASSAAD: A little bit. I didn't take a shower this morning, so it might be less than most.

BY MR. C. GORDON:

Q. So a hospital experience as a single surgical site infection involving Staph epidermitis, that wouldn't be the type of thing that would result in CDC getting a call and starting an outbreak investigation; right?

MR. B. GORDON: Object to the form. Calls for speculation, the source of the outbreak.

THE WITNESS: Well, if it was the infecting pathogen, I think it's probably unlikely that it would lead to a CDC investigation. On the

other hand, if it were Staph epidermitis that had a very unusual antibiogram, for instance, so --

(Reporter asks for repetition.)

Antibiogram. So, for instance, when the first reported Staph aureus or MRSA that had vancomycin intermediate resistance --

(Reporter asks for repetition.)

Vancomycin intermediate resistance occur it was N of 1. And we investigated to try to identify what was going on.

Now, if it had been an MRSA or a Staph aureus with a very common antibiotic susceptibility pattern, we wouldn't have investigated probably.

BY MR. C. GORDON:

Q. And take away from that what the CDC investigates is unusual circumstances. A cluster of more infections than you would normally expect for an unusual type of pathogen.

MR. B. GORDON: No question yet.

BY MR. C. GORDON:

Q. Right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, it's a combination of factors. So it's unusual -- or I mean, it's an unusual antibiogram association with a medical

device that's not been known to be a source before like the heater-cooler. So there's a list of different possibilities of what would be investigated. But certainly every infection that occurs would not be investigated.

BY MR. C. GORDON:

Q. So the fact that 20 of the 21 investigations that you referred to that the CDC investigator proved to be exogenous sources, are you saying that that tells you that all the infections that you didn't investigate must also be predominantly exogenous?

MR. B. GORDON: Objection to form. Misstates his testimony.

THE WITNESS: Yeah, I wouldn't say it necessarily is -- is -- reflects that. But it does show that even though many of those were Staph aureus infections and some like Dr. Wenzel would say that's exogenous organisms. In fact, when we investigated them, they weren't. And without investigating them, you don't know.

BY MR. C. GORDON:

Q. I go back to my earlier question. Can you point me to any published medical literature in the last 18 years that says that now the majority of

SSIs are caused by exogenous sources?

MR. B. GORDON: Objection; asked and answered.

THE WITNESS: As I mentioned, that Seminars in Infection Control has a number of papers in there that would address that. I'm sure there are others in the published literature talking about the relative relationship between endogenous and exogenous sources.

BY MR. C. GORDON:

Q. When you say you're sure there are, have you done research to see if that's the case?

A. I have not looked recently. It would be pretty easy to do.

Q. But you didn't do that?

A. No.

Q. So when you said on page 5 of your report, "Exogenous sources account for the majority of SSIs," that was based on your own personal analysis; right?

A. Well, personal analysis as well as experience at CDC investigating outbreaks for 17 years.

Q. Well, you had had that experience in 1999 when you wrote, "For most SSIs, the source of

pathogens is the endogenous flora of the patient's skin"; right?

A. Well, I hadn't had it all in 1999. I had been there -- what? -- 19 -- 17 years probably when I started. It had been 19 years.

Q. Okay. And so --

A. So it was changing. And that is a reference from 1968, which is a few years before that.

Q. Well, in 1999 when you were applying the CDC gold standard methodology, I assume you took note of the fact that some study you were citing was 1968 and you would have done at least some research to see if that was still a valid study or if there were more contemporary things that called that into question; right?

A. I'm sure there was some literature reviewed, yes.

Q. And if you had found something post 1968, which challenged the statement that you put out in these guidelines, you would have at least considered it and perhaps mentioned it; right?

A. Well, we do mention in the next paragraph. It basically is a paragraph on endogenous and a paragraph on exogenous.

Q. Okay. I'm talking -- and again I understand there -- you talk about exogenous and endogenous.

You would agree with me that what you say in 1999 says that "more than 50 percent of SSIs are caused by endogenous sources." What you're saying now in this expert report is that more than 50 percent of SSIs are caused by exogenous sources; right?

MR. B. GORDON: Objection to form. And you're misquoting the citation you're referring to now, Corey. You're using "causes" instead of "sources." And before you were saying "sources." So just be clear for the record exactly what you're asking him.

BY MR. C. GORDON:

Q. And I'll accept that as a friendly amendment. My question relates to "sources," not "causes."

A. Okay. I think what we were trying to do in the SSI guideline is basically point out that both endogenous and exogenous sources of pathogens are important in patients undergoing SSIs.

The other thing is that this guideline is a guideline for all SSIs, not specific to prosthetic

joint infections. And so there's a difference there as well. We're not talking specifically about prosthetic joints. We're talking about all SSIs.

Q. Okay. Let's look at the very next sentence. I'm sorry. Not the very next sentence. Couple of sentences down where you talk about seeding of the operative site from a distant focus of infection. Do you see that?

A. No. Which page are we in?

Q. It's on page 103. It's on the right-hand -- top of the right-hand column. I'm sorry. On the 1999 guidelines. Exhibit 5. The paragraph on endogenous sources. Towards the end you're talking about seeding of the operative site from a distant focus of infection.

A. Right.

Q. That would be an endogenous source; right?

A. Well, seeding could be endogenous or exogenous.

Q. Okay. What is seeding? What does that mean?

A. Basically means there's a source of the organism and the organism then gets in from that source into the prosthetic joint.

Q. So how could there be an exogenous

seeding?

A. Well, it could be like the Bair Hugger where it's blowing contaminated air or excess heat is changing the ventilation with convection and bringing organisms from the flora. That would be seeding. Seeding is basically that the organism gets into the wound.

Q. What is -- I'm sorry. What is -- what does the phrase "distant focus of infection" mean in that sentence?

A. Well, that particular sentence, "seeding of the operation site from a distant focus of infection," is talking specifically about patients that would have, say, an abscess somewhere else, would be one possibility; other would be colonization.

Q. All endogenous; right?

A. Those would be endogenous, yes.

Q. All what the patient brings to the table; right?

A. That's one possibility, yes.

Q. Okay. And in 1999, you said that that seeding from distant focuses of infection was particularly -- occurred particularly in patients who have a prosthesis or other implanted -- implant

placed during the operation; right?

A. Correct.

Q. And so you -- in that particular sentence there's no question in your mind, you're saying that this issue of seeding from a distant focus of infection, that can cause SSIs but particularly can cause SSIs in cases -- in the case of implants; right?

MR. B. GORDON: Objection to form, counsel's characterization of cause which is source.

THE WITNESS: Well, if you look at most of the references, most of the references are talking about patients who have had a bacteremia. So one is prosthetic valve endocarditis. Another one is about hematogenous spread of bacteria. Another one is about bacteremia. So they're not really talking, in terms of references, about a patient who happens to be colonized with Staph aureus and gets a Staph aureus infection. They're virtually all -- let's see. Most of them are secondary to bacteremia.

BY MR. C. GORDON:

Q. What's reference number 60? What's that about?

A. Well, I think reference 60 is talking about the important role of prophylactic

antibiotics; in this case, hip replacement procedures.

Q. Well, how does it support the statement that you made that "seeding of the operative site from a distant focus of infection can be another source of SSI pathogens"?

A. Well, I'd have to go back and pull that paper. But my guess is that that one is showing that if prophylactic antibiotics are given as the right drug at the right time at the right dose, that they reduce the risk for infection even if you have a bacteremia or other endogenous source. Or even exogenous source.

(Exhibit 16 marked.)

BY MR. C. GORDON:

Q. Show you Exhibit 16. Is that the cite?

MR. B. GORDON: Can I have a copy?

MR. C. GORDON: No. Sorry. I don't have one.

THE WITNESS: (Witness reviews document.) Okay.

MR. C. GORDON: Was there a -- was there a question pending? Or the question right before he said he had to look at the study.

(Record read as follows:

"Q. Well, how does it support the statement that you made that 'seeding of the operative site from a distant focus of infection can be another source of SSI pathogens'?")

THE WITNESS: As I say, I think they were specifically looking at -- in this paper at the role of prophylactic antibiotics. And it seems like they were also talking about the fact -- at least there's mention of the fact -- that the wound is -- where did they say it?

So they don't really say that much about the source. They really in this paper are looking at early infections versus late infections and whether the prophylactic antibiotic has an impact on both.

BY MR. C. GORDON:

Q. Let's go back to Exhibit 5, the 1999 guideline. Still on page 103. Back to the beginning of that paragraph on endogenous sources. In the second sentence you say, "When mucous membranes or skin is incised, the exposed tissues are at risk for contamination for endogenous flora."

Did I read that correctly?

A. You did.

Q. What does that mean?

A. Means that the patient's own skin flora can be a source of contamination and that's why we emphasize the importance of chlorhexidine bathing before surgical procedures in use of chlorhexidine with alcohol preferably for skin prep. And, as that paper shows, the importance of prophylactic antibiotics and reducing the risk of those infections from occurring.

So that whole part of what's now called SSI prevention bundles are really aimed at preventing those endogenous infections or infections from a patient's own flora. It also gets to potentially screening for MRSA or MMSA and decolonization with mupirocin and, again, chlorhexidine.

(Reporter asks for repetition.)

Decolonization with mupirocin -- M-U-P-I-R-O-C-I-N. Chlorhexidine.

Q. All of those things can have a beneficial impact on the risk of a joint infection; right?

A. Well, some are proven more than others. But the aim of those things is to reduce the impact of endogenous flora and causing infections.

Q. Are there any -- any of those things that

you would recommend not be done for orthopedic implant patients? Any of the things you just mentioned as part of the SSI prevention bundles?

A. I think they're all important, but there are some areas of debate or controversy.

Q. When the -- well, let's back up.

When you prepare the skin, whether its chlorhexidine or povidone iodine or whatever, all it can do is decontaminate the surface layer of the skin; right?

A. Well, its primary impact is on the transient flora; correct.

Q. Well, there can be transient flora that are -- that are in the hair follicles or sebaceous glands; right?

MR. B. GORDON: Object to the form.

THE WITNESS: They definitely can be. And some of those are removed and some are not.

BY MR. C. GORDON:

Q. Is that one of the reasons why you -- and I there's actually unanimity in the -- among all of the experts in this case that chlorhexidine gluconate is the preferred skin prep for surgery because it can --

A. Well, I would say chlorhexidine with

alcohol.

(Reporter asks for repetition.)

Chlorhexidine with alcohol. Because alcohol has an immediate effect and chlorhexidine has an immediate and a long-term effect.

(Reporter asks for repetition.)

Chlorhexidine with alcohol. Because alcohol has an immediate effect and chlorhexidine has both an immediate and long-term effect.

Q. Is part of the long-term effect associated with chlorhexidine the fact that it may get down into hair follicles and sebaceous glands over time?

A. Yeah, I don't know how good those data actually are. Primary reason for chlorhexidine having benefit over, say, povidone iodine is --

(Reporter asks for repetition.)

-- povidone iodine is that chlorhexidine's spectrum of activity is better for gram-positive organisms; whereas, povidone iodine activity is better for gram-negative organisms.

Povidone iodine is inactivated by proteinaceous material. Chlorhexidine is not. And chlorhexidine binds to the skin. So the fact that you have blood and proteinaceous material during a surgical procedure makes chlorhexidine preferable to

povidone iodine.

I'm not sure that there are any data that it actually seeps into the hair follicles and sebaceous glands and reduces those organisms more, but they certainly would have binding of the skin. And so it has a longer impact than something like povidone iodine that you put on and, basically, if it has contact with proteinaceous material, it's inactivated and done with.

Q. So would povidone iodine be effective against Staph aureus?

A. It can be. But chlorhexidine probably has better activity.

Q. So if an orthopedic implant patient is prepped with povidone iodine, there's a greater risk that they're going to have residual Staph aureus on their skin than if they're prepped with chlorhexidine?

MR. B. GORDON: Object to the form --

BY MR. C. GORDON:

Q. Perhaps?

MR. B. GORDON: -- counsel's testimony.

THE WITNESS: Well, I think you have to look at, number one, is it povidone iodine alone, or is it povidone iodine with alcohol? Because alcohol

obviously has an immediate effect. And most of the studies looking at either skin prep or surgical prep with chlorhexidine versus povidone iodine, were chlorhexidine with alcohol versus povidone iodine without alcohol. So it's two agents on one side and one on the other; so it's kind of a little bit unfair.

As far as I know, there's only been one randomized control trial of chlorhexidine with alcohol versus povidone iodine with alcohol. And that was with catheter and -- vascular catheter insertion. Where chlorhexidine with alcohol was found to be superior.

There's actually one before/after study at Dr. Wenzel's former hospital, University of Virginia, looking at povidone iodine with alcohol versus chlorhexidine with alcohol. It showed chlorhexidine with alcohol was superior.

Q. Would you agree that the more bacteria you remove from the skin, the less chance there is of re- -- any residual bacteria migrating into the site once the skin has been incised in -- in joint surgery?

MR. B. GORDON: Object to the form. Lack of foundation.

THE WITNESS: I think that might be a -- kind of a commonsense belief. Chuck Edmondson has done a lot of studies of chlorhexidine as a skin prep. And talking to him a couple of weeks ago, his belief is that actually two applications is sufficient and not that, you know, if you did five applications you'd be better.

BY MR. C. GORDON:

Q. Again, I -- sorry. I moved on beyond the issue of what's the better -- what's the best skin prep. My question goes to the -- just the number of bacteria on a person's skin.

A. But that's --

Q. All other things being equal, if there -- if person X has more bacteria on his skin than person Y, person X is at greater risk of a joint -- a PJI than person Y --

MR. B. GORDON: Object to the form --

BY MR. C. GORDON:

Q. -- from those bacteria; right?

MR. B. GORDON: Object to the form and counsel's preamble.

THE WITNESS: Yeah, I guess I would say that as this document, the guideline, states, there is endogenous organisms and there's exogenous

organisms. And you and Dr. Wenzel are ignoring totally the exogenous. And I would say that regardless of how many bugs you have on your skin, if you're going -- undergoing a prosthetic joint procedure, if there are two people in the room versus there are 10 people in the room, that's probably a much more important factor. You're not jumping around; they are. You're not having your skin squames -- S-Q-U-A-M-E-S -- being aerosolized all over the place.

You as the patient having surgery have had hopefully chlohexadine baths, you had chlorhexidine with alcohol or some good skin prep that's killed a lot of the bugs that you have on you. Whereas, all those people around you in the surgical procedure have not had any of that and are disseminating organisms.

And that's why a device like the Bair Hugger, when it has all that heat that's being released underneath the operating room table and has the possibility with convection currents to bring that up over the operative field, that exogenous source ends up being more important than the endogenous source.

MR. C. GORDON: Move to strike as

nonresponsive.
Q. Again, all I'm asking is -- about comparing one patient to another, everything else being equal. If patient X has more bacteria on his skin at the site of the incision than patient Y, patient X is at a greater risk of a deep joint infection than patient Y --
MR. B. GORDON: Object to --
BY MR. C. GORDON:
Q. -- from those bacteria; right?
MR. B. GORDON: Object to form. And asked and answered.
THE WITNESS: I guess I would say that might be theoretically true; I'm not aware of any study that's done that. It's actually a very difficult study to do. You'd have to do quantitative counts on the skin of the patient. You'd have to do those by species. And that's a very difficult study, very expensive study to do. And I don't know of any data that has -- any study that's done that and, in addition to doing that, has also followed those patients for surgical deep joint prosthetic joint infections and done genomic typing and correlated the two. And you would really have to do that to answer that question.

BY MR. C. GORDON:
Q. Skin -- or -- strike that.
Bacteria that remain on the skin after skin prep, if they're right at the site of incision, can migrate to the joint implant; right?
MR. B. GORDON: Objection to form. Assumes facts not in evidence. Lack of foundation.
THE WITNESS: Again, it's theoretically possible. But if they're using something like an Ioban drape, you've basically covered that whole area --
(Reporter asks for repetition.)
Ioban, I-O-B-A-N.
Where you have basically a povidone iodine-impregnated plastic sheet that's going over the patient and doing an incision through it. So you literally have almost no skin that has any exposure to the operative site. So if you had tons of bugs versus no bugs, how -- what are they going to do, jump through the plastic sheet and jump around? They can't.
BY MR. C. GORDON:
Q. I'm talking about the residual bacteria in the sebaceous glands in the hair follicles and the lower dermal layers.

MR. B. GORDON: Objection to form. Assumes facts not in evidence.
BY MR. C. GORDON:
Q. Does the Ioban drape kill all those bugs too?
A. They don't maybe kill all of those bugs, but they are basically minimizing the amount of exposure that the wound has to skin, period.
Q. So help me understand what you are saying here. In Exhibit 5, "When mucous membranes or skin is incised, the exposed tissues are at risk for contamination with endogenous flora."
A. I think that goes back to that 1968 article and basically talking about organisms that are on the patient's skin.
Q. Actually that particular statement goes back to a 1978 article; right?
MR. B. GORDON: '79.
MR. C. GORDON: '79.
THE WITNESS: Thank you. At 58 or 56?
MR. ASSAAD: Hey, Corey? Maybe we can take a break. Don't forget about what the court reporter needs. With all these words, she might need a break at some point.
MR. C. GORDON: Mr. Staph Epidermis [sic]

wants a break. So --
MR. ASSAAD: I don't need a break at all. I just -- I feel that she's been having trouble with all these words; she might need a break.
MR. B. GORDON: You don't have to take all this down. This is off the record.
If you want.
MR. C. GORDON: Yeah, that's fine.
Heidi, did you need a break?
THE REPORTER: Yeah, that would be great.
THE VIDEOGRAPHER: The time is 2:01 p.m. We are off the record.
(Recess taken from 2:01 p.m. to 2:12 p.m.)
THE VIDEOGRAPHER: This marks the beginning of Volume I, file 4 in the deposition of Dr. William Jarvis. The time is 2:12 p.m. and we're on the record.
BY MR. C. GORDON:
Q. Dr. Jarvis, just to be clear, have you written anything other than your expert report, Exhibit 1, since you did the CDC guidelines in 1999 where you have concluded that exogenous sources now account for the majority of SSIs?
A. I certainly have written many, many things since 1999 regarding surgical site infections. I

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would have to look and see if I have that specific sentence in them or not. Certainly the Seminars in Infection Control have an entire paper on the role of environment. So --

(Exhibit 17 marked.)

BY MR. C. GORDON:

Q. Okay. I'm going to -- just so the record is clear, I'm going to give you Exhibit 17. Is that the infection control paper you've been referring to? Or you just referred to?

A. (Witness reviews document.)

Q. Is it -- is that Exhibit -- what was it, 17? Is that the one you were just talking about?

A. Yes.

Q. Okay. Is the -- what chapter is it that you said dealt with -- was it environmental factors?

A. Well, outbreaks associated with environment and outbreaks associated with medical devices and medications. Both talk about exogenous sources.

Q. Okay. Let's start with outbreaks associated with the environment on page 1- -- starting on page 124.

You -- you were one of the authors of this chapter; correct?

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A. Correct.

Q. Okay. And under "Air," could you list off the infectious pathogens that you discuss.

A. Well, we talked specifically about outbreaks. So TB, measles, varicella, potential bioterrorism agent such as smallpox, influenza, Legionnaires, Pontiac fever.

Q. Okay.

A. So those are the ones that we focused on because of the fact that they were associated with outbreaks, as well as fungal infections.

Q. Right. And just -- I'm curious. You know, you wrote it, so you tell me. Is there anything else in this chapter that talks about airborne pathogens that could -- could relate to peri-prosthetic joint infections?

A. Well, it also talks about MRSA on page 127.

And under "Prevention" it talks about adequate installation, regular monitoring, preventive maintenance of HVAC systems are required to ensure that systems function -- function properly and minimize the risk of pathogen transmission to patients and staff. So there's a whole paragraph talking -- two paragraphs, actually, talking about

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the importance of HVAC systems in preventing infection, but it doesn't specifically mention prosthetic joints.

Q. Well, in -- on page 127 where you talk about MRSA, what is the mode of transmission you discuss? Or the mode of spread? Excuse me.

A. Airborne spread?

Q. Yes.

MR. B. GORDON: I think he answered you, Corey.

BY MR. C. GORDON:

Q. Just ventilation; right?

A. Well, it talks about the fact that MRSA has been documented to be spread by the airborne route.

Q. From ventilation; correct?

A. Correct.

Q. That's --

A. Ventilation grilles, exhaust.

Q. Ventilation grilles and exhaust ducts; right?

A. Right.

Q. And you note that other well-established modes of transpor- -- transmission such as transient hand carriage by healthcare workers were not

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investigated or eliminated; is that correct?

A. Correct.

Q. So is -- would you agree that there are other well-established modes of transmission of Staph aureus?

A. Oh, absolutely, yeah. On hand transmission as well as being aerosolized from patients to other patients, as well as in the operating room.

Q. When CDC would do an outbreak investigation, how would you go about assessing whether the outbreaks were coming from any of the well-established modes of transmission?

A. Well, it was part of that gold standard approach that I talked about. So it would be, you know, reviewing cases, doing line listings, doing epidemiologic studies to look at risk factors. And then based on that epidemiologic data, doing either personnel or environmental cultures. Looking at a variety of potential sources. And then probably doing molecular typing of the organisms to see if they were the same or not.

Q. And the reason you do that or would do that for joint infections is that there are a myriad of potential sources; right?

MR. B. GORDON: Objection to the form. Also mischaracterization.

THE WITNESS: Well, there are certainly many endogenous and exogenous source possibilities. Some of which are -- or many of which you hopefully can eliminate.

BY MR. C. GORDON:

Q. And the only way you can eliminate them is if you investigate them; right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, you can do -- it depends on if it's a cluster or an individual case. Obviously if it's a cluster, trying to do an epidemiologic study can assist you in identifying whether it's personnel that are the source or potentially the patient or equipment.

BY MR. C. GORDON:

Q. And how do you do that in an individual case?

A. It's a little bit more difficult, but you look -- I think in the individual case, you also focus on kind of the timeline of events of what has happened and looking at all the different prevention interventions, some of which we've talked about such as skin prep, timing of prophylactic antibiotics,

breaks in aseptic technique, the duration of the procedure. So a lot of individual factors that may either increase or decrease the risk for infection occurring.

MR. B. GORDON: For the record I want to interpose an objection here.

I'll give you some latitude, Corey, but we're to talk about general causation today. There is a thing contemplated the other day for case-specific causation. Will be a different report, different deposition. But if you want to ask those questions today, then we're going to take the position that you're done after today.

BY MR. C. GORDON:

Q. Going back to -- I want to look back on page 127 where you talk about other well-established modes of transmission such as transient hand carriage by healthcare workers. How could you -- how -- what was your -- what -- strike that.

You -- you do say here that in outbreaks those were not investigated or eliminated. Would there have been a methodology for investigating or eliminating those?

A. Well, you could follow the same pattern of, you know, medical record review, and line

listing, epidemiologic studies to try to identify what the risk factors for infection are. And there certainly would be some ways to try to address that. It's obviously -- if the outbreak is ongoing, and it's probably easier to do than if the outbreak stopped two weeks ago. So it's a little -- the type of the investigation tends to be tailored to the specific outbreak and the timing of that outbreak and what's available, what's not as to what you can do.

Q. How do you define an outbreak?

A. Well, I think the generally accepted definition is it's the frequency of occurrence of an event that is above the baseline rate and reaches a statistical significance. And that's usually the definition that is used. And there is somewhat a differentiation of "epidemic" or "outbreak" from "endemic." So a lot of the infections that occur are endemic infections, particularly if it's a patient's own endogenous flora.

And so if you look at a hospital within, say, MRSA infection rate, they've got a long period of time where they've had MRSA infections and there's some kind of background rate of what that is. With an outbreak, it assumes that you have that

background rate or can calculate that background rate and then look at what the rate of event is during a putative outbreak period and then do a statistical analysis to see if the rate is increased statistically.

Q. One of the papers that you rely on for your opinion is the McGovern 2011 study. We talked a little bit about it earlier. It had bubble component to it. And it also had a -- an observational study component to it; correct --

MR. B. GORDON: Object to the form --

BY MR. C. GORDON:

Q. -- do you agree?

MR. B. GORDON: -- counsel's use of the word "reliance" -- "reliance" or "relied on," something like that.

What's the question?

BY MR. C. GORDON:

Q. Well --

A. The question was whether they had two components or not?

Q. Do you rely on the McGovern study?

MR. B. GORDON: Objection to counsel's characterization, use of the word "rely."

THE WITNESS: As I said before, I look at

all of the papers that I've read, my experience; you know, 23 years at CDC, both in terms of outbreak investigations, developing surveillance definitions, assisting with the development of the surveillance system and knowing surveillance data. All of that is incorporated in how I look at the data and how I reach the conclusions in my report. So certainly the Albrecht study was one of many that I looked at that --

BY MR. C. GORDON:

Q. You mean the McGovern -- well, Albrecht was an author. You're talking about McGovern?

A. McGovern was one of many that I referenced in my report.

Q. Was there any other study that you referenced in your report that purported to show a relative risk of Bair Hugger versus some other warming modality in terms of joint infections?

A. No. That was -- that was the solid one.

Q. So you -- before -- I assume before you decided whether that was something worthy of your inclusion in your report, you wanted to -- see if I can find your exact phrase -- you wanted to look critically and evaluate all the data, not just some of the data; right?

A. Correct.

Q. So did you do that with the McGovern paper?

A. Yes.

Q. Okay. Well, did you -- in considering the McGovern paper, did you look at the specific pattern of infections?

A. I'm not sure what you mean by "pattern."

Q. Well, the -- okay. Did you -- when you were looking critically in evaluating all the data, did you look at the individual infection types that were occurring during the study, the two arms of the study period?

A. When you mean infection types, you mean the pathogens?

Q. The pathogens, the bugs.

A. I certainly looked at that, yeah.

Q. And how did -- well, what -- what did you look at to -- to assess that?

A. You mean specifically what did I look at?

Q. Right. Are you talking about just what was printed in the study, or did you look at anything else?

A. I looked at a line list that I believe was one of the exhibits.

MR. C. GORDON: See if this helps.

(Exhibit 18 marked.)

BY MR. C. GORDON:

Q. I'll show you what's been marked as Exhibit Jarvis 18. Previously marked as McGovern Exhibit 16.

A. Yeah, that looks like it.

Q. So you reviewed this in your -- looking critically in evaluating all the data of the McGovern study; is that right?

A. Right.

Q. Did you -- let's focus on Staph aureus, both methicillin susceptible and methicillin resistant.

Did you look at the number of Staph aureus cases that occurred during the Bair Hugger-only period and compare that to the number of Staph aureus cases that occurred during the HotDog-only period?

A. Yes.

Q. And what did you find?

A. First of all, I found that my eyes are not good and I needed a --

Q. Copy that.

A. -- magnifier for this thing. That was the

first thing I learned.

Second I learned that it's hard to read and there's duplication of information in it. And I believe that -- I'm trying to see the -- I had them lined up so it made it easier to see. But I guess over here is -- that during the HotDog period, there were infections caused by Staph epidermidis, Enterococcus but none by Staph aureus.

Q. And during the HotDog -- strike that.

So during the HotDog period there was zero Staph aureus infections; correct?

A. There were only three infections but, yeah, none were Staph aureus.

Q. And you read Dr. Reed's testimony where he said there should have been an additional infection in the HotDog --

A. Right.

Q. -- arm, correct?

A. Right. I don't know what the pathogen was with that one. It might have been Staph aureus; I don't know.

Q. And in the Bair Hugger-only period, how many Staph aureus infections were there?

A. I don't know that I counted them.

MR. B. GORDON: Just for the record while

he's counting or looking at, object to all of this as -- I don't know if this has been authenticated, Corey, but all this data as being of uncertain veracity. I don't know anything about where it came from. Has this been authenticated by anyone?

MR. C. GORDON: It was produced by Dr. McGovern.

MR. B. GORDON: All right. Well, I just want to object for the record.

THE WITNESS: I believe 19. But I could have counted wrong.

BY MR. C. GORDON:

Q. Well, in terms of the total number of infections attributed to the Bair Hugger-only period, whether it's 19 or 18 or 20, would you agree that the Staph aureus constituted the majority of infections in the Bair Hugger-only period?

A. I think so. Yes. There's a lot of coagulase negative Staph as well.

(Reporter asks for repetition.)

Coagulase negative Staphylococcus.

MR. B. GORDON: And again I want to object for the record to the extent we don't know if this is the final data or not which could change the results.

BY MR. C. GORDON:

Q. And focusing for a moment just on the Staph aureus where the majority of the Bair Hugger-only and none of the HotDog-only, are you aware of any interventions that occurred at Northumbria during the Bair Hugger period or prior to or during the HotDog period that would have preferentially had an impact on Staph aureus?

A. Well, I'm aware that they began a -- what they call, I think, an MSSA screening protocol which, you know, one could argue might have an impact. First of all, they talk about the screening, but they don't talk much about what they did with the screening. But let's assume they did some kind of decolonization.

Q. Did you read Dr. Reed's testimony about what they did when there was a positive MSSA screen?

A. I'm trying to remember if I did or not.

Q. Well --

A. I think they -- I think he may have mentioned using mupirocin.

(Reporter asks for repetition.)

Mupirocin. M-U-P-I-R-O-C-I-N.

And I can't remember about chlorhexidine. But even given that, Dr. Wenzel did a

randomized control trial and showed that it didn't have any significant impact on MSSA.

Q. Do you advocate MSSA screening for joint arthroplasty?

A. Certainly if I were having a joint procedure I would request it. Is it a consensus among orthopedic surgeons or infectious disease colleagues? No.

Q. They went to a chlorhexidine skin prep too at some point; correct.

A. Correct.

Q. Did they -- were there any additional Staph aureus infections after they switched to the chlorhexidine prep?

A. I would have to look back to see what the date was of when they changed that.

Q. I guess my bigger question is did you do that? Did you correlate the dates with the changes?

A. I probably did write it down somewhere.

Q. Well, you know, your counsel gave me -- this morning gave me copies of some notes. Let's go ahead and mark those and see -- if they're in there, great; if not, then not.

(Exhibits 19 - 20 marked.)

BY MR. C. GORDON:

Q. Showing you Exhibits 19 and 20. What are these documents?

A. 19 looks like it's copies of my notes from the various depositions.

And 20 is kind of a compilation of things. So it includes listing of a variety of different issues such as contaminated Bair Hugger units in the 1, 2, 3, 4, 5, 6 studies that document that. The increase in particles in the sterile field with Bair Hugger in the 1, 2, 3, 4, 5, 6 studies documenting that. The impact of the Bair Hugger on disruption of laminar flow on 2, 3, 4 studies documenting that.

A few notes from clinical director Van Buren [sic] from 3M talking about the growing concern about infection potential of the Bair Hugger. And that he acknowledges decreased particulates would lead to decreased SSI risk.

And then a comment from an e-mail, I believe it was, from -- I'm not sure how you pronounce her name Hulse-Stevens or Sterums [phonetic] or something.

(Reporter asks for repetition.)

H-U-L-S-E, dash, S-T-E-V-E-N-S.

Where she went to an international

consensus conference I think of orthopedic surgeons and said there's energy around the issue of prevention of prosthetic joint infections. And the possibility that forced air warmers increased particulates and increase infection.

So there was a section on Project Ducky where they were looking at trying to incorporate HEPA filtration into the Bair Hugger but ultimately didn't do it.

Q. Let me interrupt you here because I'm a little confused. Your notes are quoting from things that I don't think on your -- either your reference list or your "Additional Materials Reviewed" list. Were you looking at a document about Project Ducky or looking --

A. I think these -- I think Project Ducky was part of a -- I'd have to go back and look, but I believe it was Van Duren or Hansen or one of the depositions.

Q. Okay. I don't see -- Van Duren's not on your list of the depositions you reviewed. So that's another question I'm curious about. But --

A. I'd have to look.

Q. Where --

A. It was definitely a 3M e-mail that I

believe was -- I think it was an exhibit on one of the depositions.

Q. Okay.

A. Van Buren may have -- I'd have to look.

Q. Can you tell when these notes were written?

A. No. I've not dated them.

Q. But do -- do either or both of those pre-date your report?

A. This -- some do, some don't.

Q. Can you tell --

A. So, for instance, this first page on Exhibit 20 is after my report. But the bottom part there, the 3M e-mails was before the report. Not written -- this part was not written but this was stuff that I already knew. Same with Project Ducky. And then the kind of the bottom two-thirds of that back of the first page is from after the report.

Q. The third page of the -- Exhibit 20, the top reference there is to Julie Gillson, October 14 article. Is that something you had read prior to your report?

A. No. No, that's after.

Q. So prior to your report, did you have any -- writing your report, did you have any

information about the various infection control practices that had been implemented at Northumbria during or prior to the -- well, at any time during the Bair Hugger/HotDog observational study?

A. I'd say if they were mentioned -- and I don't remember specifically if they were mentioned in the -- either the Reed or the Albrecht depositions.

Q. Do you recall if you learned anything after the report about infection control practices that were implemented that you -- that was new to you that you thought, oh, gee, I didn't know they did that.

A. I'm trying to think. You know, the other exhibit that I think was either Reed -- I'm not sure when that was. The graphic. I had seen that. But I can't remember if that was before the report or after.

Q. Oh. The chart?

A. Yeah.

Q. In Gillson?

A. Yeah, yeah. Because I think Gillson was like October, publication date.

(Reporter asks for repetition.)

Gillson was published in October.

Q. Regardless of source, I'm just -- what I'm really trying to understand is if after you wrote your report you saw anything or heard anything that made you go oh, I guess I didn't realize they had done X at Northumbria.

A. Not that I recall.

Q. Now going back to your definition -- the concept of an outbreak. Can you recall reading in Dr. Reed's deposition that the National Health Service in England had identified Northumbria as being a high outlier for its orthopedic infection rates?

A. I remember him talking about them getting some communication from -- I guess it's Health -- HPA. Health Protection Agency. Changed its name now to something else. And him commenting that to some extent that probably depended a bit on the surveillance done by different trusts and that some trusts -- at that point they only had to do surveillance for -- I think there were four procedures that you had to do; three months of surveillance for an entire year. So different people were doing surveillance for different procedures. The intensity of surveillance was different and we know that if you're not doing

post-discharge surveillance or comprehensive reviews really of the records, you're probably underreporting your rate. And that his feeling was that there probably was underreporting by other hospitals. And that was kind of part of the reason why their rate might look higher than others.

Q. Your -- when you did the -- your evaluation of all the data and you saw that there were 19, give or take, Staph aureus infections during the Bair Hugger period, did that strike you as a potential outbreak issue? That they had a problem with Staph aureus?

MR. B. GORDON: Object to the form. Assumes facts not in evidence.

THE WITNESS: Yeah, I don't know that I thought it was an outbreak issue because there's certainly -- you've got a group at the very top at the beginning that are kind of one after another, but then the others are kind of scattered around. So -- and -- and certainly in his deposition he didn't acknowledge any specific outbreak that was -- that was occurring. And obviously Staph aureus, coagulase negative Staphylococci are the number one and two most common organisms to cause prosthetic joint infections. So you wouldn't expect that there

would be a list of you know, Aspergillus; and Burkholderia, and Acinetobacter, and a lot of other organisms. And really the only way to know would be to do genetic typing of those organisms.

BY MR. C. GORDON:

Q. That's the only way you can link up a specific --

A. That's one way --

Q. Let me finish the question.

-- a specific infection and a specific source; right?

MR. B. GORDON: Object to the form and beyond the scope of this deposition.

THE WITNESS: That is one of the ways. One of the messages from the outbreak investigations that we did was that epidemiologic methods really trump laboratory methods. And that's why we've always recommended not doing just culture surveys. A lot of times a cluster will occur and what I describe in my report and in these papers is, quick and dirty is, for infection control people just to go around and start culturing all sorts of stuff and send it to the laboratory. It's relatively easy for them to do. Puts the burden on the laboratory. And usually doesn't identify the source. So doing a

good epidemiologic investigation almost always identifies the source. And then the laboratory either cultures and/or typing confirms that.

BY MR. C. GORDON:

Q. And when you do a good epidemiological survey, specifically looking at joint infections, you want to consider every possible factor; right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, I guess it depends on what you mean by consider. Certainly one of the things we always did for our outbreak investigations and one of the things I think you would want to do is to look at the literature. If you have a cluster of, say, Pseudomonas infections, you know, what has been described in the past as being the cause of such infections? And make sure you look at those things and exclude those things. Obviously those are the most likely sources. And unlikely sources might still be a possibility and you should evaluate them.

MR. C. GORDON: Well, let me show you Exhibit 21.

(Exhibit 21 marked.)

BY MR. C. GORDON:

Q. This is a paper you co-authored; correct?

A. Correct.

Q. And in this case you are -- you conducted -- you and your colleagues conducted an investigation into outbreak of wound infections in knee arthroplasty; right?

A. Correct.

Q. You looked at two hospitals; right?

A. Correct.

Q. You -- in the time period you looked at, there were 20 infections that you identified; right? A little under --

A. Correct.

Q. -- not quite four years. '84, '85, '86, and almost all '87; right?

A. Until November '87; right.

Q. And of those 19 -- of those 20 infections, 18 of them were deep joint infections; right?

A. I'm trying to see where it says that.

Yes. Yes. Okay.

Q. And do you know what the -- so can you -- it's not in here. I had to calculate it myself. But can you tell us what the deep joint infection rate was for knee arthroplasty in the study that you did?

A. During the epidemic period or during the

pre-epidemic period?
Q. During the -- the epidemic period, is that January 1, '84 to '87?
A. January 1, '84 to November 30, '87.
Q. Yes. During that period.
A. 7.7 percent.
Q. That was -- that included the two SSI -- superficial SSIs; correct?
A. Correct.
Q. So my question was can you calculate knowing that 18 of those were deep joint infections, what the actual deep joint infection rate was?
A. Well, if the question is can I calculate? The answer is yes.
Q. Is it about 5.8? Does that sound about right?
A. (Witness pulls out calculator.)
Q. Ah, Smartphones.
A. 6.9.
Q. So that was -- and that was just for knees; right?
A. Correct.
Q. And, in fact, you note that -- on page 906 that there were -- there was no increase in the infection rate for patients undergoing hip

replacement at these two hospitals; right? Is that right? Sorry.
A. Right.
Q. And so the -- would that be the type of situation that would result in an outbreak investigation? You've got an unusually high number of joint infections with knees but not with hips?
A. Correct.
Q. In the McGovern paper, did you notice the ratio of hip infections to knee infections?
A. Yes.
Q. Do you recall what it was?
A. I'd have to look. I think knee was higher than hip.
Q. You think knee was higher than hip?
A. I would have to look. But it was the opposite of what you said.
Q. Okay. Well, whatever it is, it was the opposite of what you would expect. Is that what you recall?
A. What's commonly found, yeah, yeah.
Q. And was it -- when you say "opposite," was it just a little bit off or was it -- was it a pretty big difference?
MR. B. GORDON: He already said he'd need

to look at the study to know for sure.
MR. C. GORDON: That's fine.
THE WITNESS: Sorry about that.
So 4.6 percent on hip; and 1.7 percent in knees.
BY MR. C. GORDON:
Q. Well, I'm looking at the bottom of page 1542 and where they say, "It was, however, somewhat unusual that the odds of infection associated with hip replacement were 4.1 times greater than the odds for knee replacement. Typically infection rates are greater for knee replacement."
Do you see that?
A. Correct.
Q. So instead of being slightly more knees, it was more than four times as many hips in this particular study; right?
A. Yes.
Q. And when you did your -- when you look critically and evaluated all the data, what -- what did you -- how did you factor in this anomaly that there were 4.1 as many -- that the odds for infections in hips were 4.1 times that of knees?
MR. B. GORDON: Object to the form, counsel's characterization.

THE WITNESS: I would say that I just -- you know, that's what happens when you do a study in a real-life situation rather than a control situation. You may find things that are slightly different than have previously been described.
BY MR. C. GORDON:
Q. Well, in the paper you did in 1990, Exhibit 21, the signal that caused the concern was that the knee rates were substantially higher than the hip rates; right?
A. Well, I think as much as anything, it was that the rate in knees was so high and that it was clustered around one individual surgeon.
Q. Well, you didn't know that going in; right?
A. Well, to some extent we did. Brian Simmons is actually the hospital epidemiologist who was at that hospital and he had been doing surveillance and actually had an idea that that was what was going on and felt that he would be able to deal with the surgeon, if you will, if CDC came in and confirmed what he initially had found and helped him.
Q. So he had a surgeon that he suspected was a problem?

A. Correct.
Q. Was this surgeon doing both hips and knees, or was he only -- he or she only doing knees?
A. I don't remember.
Q. Do you have any reason to -- strike that.
Do orthopedists who do implant surgery always do both hips and knees? Or are you aware of some who do predominantly one versus the other?
A. I've never seen a survey of orthopedic surgeons to answer that. My guess is some -- some do both and some prefer doing one or some prefer doing the other.
Q. To sort of cut to the chase on your study in Exhibit 21, the -- one of the two factors you identified as being strongly associated with the abnormal increase in knee infections was this one surgeon; right?
A. Correct. And his rate was literally 9 times, almost 10 times any other surgeon. So he really stuck out. It wasn't a 4 to 1. It's 2 and a half times that. And this is not just one surgeon.
Q. How many surgeons are involved in the McGovern study?
A. I'm not sure. I thought I saw either -- one of the depositions I thought he said it was like

four or five surgeons, but I'd have to go back and look at that.
Q. Okay. And did all of the surgeons do roughly an equivalent number of hips and knees or --
A. I don't -- that certainly wasn't in the paper.
Q. So whether there was one surgeon who was doing a whole lot more hips than other surgeons you don't have any knowledge one way or the other?
A. No. And certainly I would assume they looked at -- you know, one of the things you would look at in, you know, doing an analysis of surgeons look at surgeon-specific --
(Reporter asks for repetition.)
Look at surgeon. Look at surgeon-specific infection rates. I don't see that reported here. But they may have looked at that.
Q. Well, you say you assume that. Do you have -- as you sit here today, do you have any basis whatsoever to testify either that they did or did not give any consideration to surgeon-specific rates?
A. Well, I don't know what they gave consideration to. I think it would be something you would look at and a surgeon would look at. But they

certainly haven't described it in the paper.
Q. Or in any deposition testimony that you're aware of?
A. Not that I recall, no. I don't remember them being asked that either.
Q. Okay. And based on your study as well as others, the surgical skill of a given surgeon can have a huge impact on the joint infections; right?
MR. B. GORDON: Object to form. Lack of foundation.
THE WITNESS: Well, surgical skill is obviously very important. You hope that the surgeon-specific infection rates are clustered very closely in terms of rate and not like this where you have one at literally 10 times the rate of the others.
BY MR. C. GORDON:
Q. So I think it was 9 times. So 9 times the rate is -- is -- that's -- that's a serious issue. But 4 times the rate would not be in your mind?
A. Well, it's 9.4.
MR. B. GORDON: Objection to form.
BY MR. C. GORDON:
Q. Okay. So 10 times --
A. They say it's 2 and a half times 4, but --

Q. But if somebody -- when you were at the CDC and somebody called and said, you know, boy, we've got four times as many hips getting infected as we do knees, you would have said well, that doesn't mean anything?
MR. B. GORDON: Object to form.
THE WITNESS: Oh, no. We would give them advice on what to look at. And one of the things would be surgeon-specific infection rates. Many times that's done and that's not the cause; you know, that's --
BY MR. C. GORDON:
Q. Okay. There are other things that you tell them to look at; right?
A. Well, absolutely.
Q. Let's take a look at your article on page 906. One of the things you did through your comprehensive analysis to try to figure out what's going on in this particular -- in those two hospitals was you pulled the medical records and reviewed those records on all the patients; right?
A. Well, not all the patients; all the study patients.
Q. All the study patients, right.
And you looked at their age; right?

A. Correct.
Q. Their sex?
A. Yes.
Q. The etiology of the underlying joint disease?
A. Yes.
Q. Whether they had prior knee surgery?
A. Yes.
Q. The American Society of Anesthesiologists ASA classification of preoperative physical status?
A. Yes.
Q. Let me stop there for a second. What is the ASA classification of preoperative status?
A. It's a core that anesthesiologists give patients that basically is kind of a health assessment. So if you have chronic disease, chronic lung disease, diabetes, peripheral vascular disease you're going to have a higher score than if you are a healthy 18-year-old.
Q. Would that -- would that be one way of assessing a patient's fitness for surgery?
A. Well, most patients also get a, you know, preoperative evaluation by an internist in terms of that. So if they had cardiac disease, somebody signs off saying they're fine, usually not the

anesthesiologist during that. It's more a way to categorize patients.
Some have used it or thought of it as kind of a severity of illness measurement. But it doesn't work very well for that because anesthesiologists probably for medical/legal reasons tend to upgrade patients to make them look like they're sicker. So if they dropped dead in the middle of surgery they can say yeah, look, their ASA score was 4; what do you expect?
Q. So in your study, Exhibit 21, the -- in addition to the surgeon-specific factor, the other factor that you found was strongly associated with the increased risk was patients who had an ASA rating of 3 or higher; right?
A. Correct.
Q. And that -- that's -- you know that that's not unusual; that the correlation between ASA and joint infections, that's been replicated in lots of other studies; true -- correct?
A. Well, certainly. The higher the ASA the more complications you might expect.
MR. B. GORDON: I just -- I'm sorry to interrupt you, Corey, but I'll put a continuing objection on the record for this line of inquiry is

going to case-specific diagnostic information. That is not the purpose of his report or this deposition. This is a general causation report and deposition. And I just want to make it clear that we're going to reserve our rights to the extent that you are using your time for case-specific causation issues.
BY MR. C. GORDON:
Q. Did the McGovern study consider any form of classification of preoperative physical status comparable to an ASA score?
A. Well, I don't know what additional materials they might have abstracted or collected or analyzed. It's not a part of -- at least not reported in their Table 2 of the univariate factors.
(Reporter asks for repetition.)
Univariate. U-N-I-V-A-R-I-A-T-E.
Q. Well, in fact in the McGovern paper, they say on page 1543, "We were unable to consider all factors that have been associated with SSI as the details of blood transfusion, obesity, incontinence, and fitness for surgery which have been identified elsewhere is important predictors for deep infection were not sufficiently detailed in the medical record."
You see that?

A. I'm trying to find that. 43?
Q. 1543. First full paragraph -- In the middle of the first full paragraph there.
A. Correct. You read that correctly.
Q. So not only is there no indication that they did consider it, there's a -- there's a express indication that they did not consider patients specific factors?
A. Or weren't able to get it, yeah. Right.
Q. So in your -- but in your study, that was one of two significant factors that accounted for the infections; right?
A. One of three factors.
Q. The -- right. And we'll get to the third factor. But ultimately that you decided -- you concluded that that one by itself was not -- well strike that. We'll come back. We'll talk about that.
Going back to what else you looked at after the -- you looked at the results was preoperative hematocrit? Right?
A. Correct.
Q. And you looked at the use of steroids; right?
A. Right.

Q. You looked at the presence of diabetes; right?
A. Right.
Q. You looked at the use of insulin; right?
A. Which would correlate with the diabetes, yes.
Q. Right.
You looked at evidence of nosocomial infection; right?
A. Right.
Q. You looked at the specific operating room; right?
A. Right.
Q. You looked at the time of the day of the operation; right?
A. Right.
Q. Why did you look at the time of day?
MR. B. GORDON: Again, I want a continuing objection on all of this going to case-specific inquiry concerning opinions about case-specific causation.
Go ahead, Doctor.
THE WITNESS: Because in some outbreaks that we've investigated, time of day ended up being important. Particularly the first case of the day.

Particularly if the first case of the day is on a Monday after the operating room has been, quote, closed down over the weekend. So it can lead to issues related to the heating, ventilation, and air-conditioning system and its functioning.
Also we had an outbreak where first cases of the day were at increased risk because of housekeeping when they were doing the cleaning of the operating rooms at night, the anesthesiology personnel had IV and other equipment set up for the first case of the day. And the housekeeping people were kind of whipping the mop around and getting water and contaminating the devices before the surgical procedure.
So basically our past experience in investigating outbreaks we found a number of times that time of day and even day of the week might be important factors to look at. So we looked at them.
Q. Have you seen studies that have gone the other way? You're -- the puzzled look you're seeing is -- I thought the consensus was that you were better off to have the surgery early in the day rather than later after other procedures.
A. That's probably anecdotal. All I can say is from the outbreaks that we investigated that

those were a couple of things that we found.
Q. Okay. So you looked at the type of knee pros- -- the knee prosthesis that was implanted; right?
A. Right.
Q. And whether it was fixed with cement or was cementless; right?
A. Correct.
Q. You looked at the number of personnel in the operating room during the procedure; right?
A. Right.
Q. You looked at the presence of assisting surgeons; right?
A. Right.
Q. You looked at whether there were intraoperative irrigations; right?
A. Right.
Q. You looked at the duration of post-operative wound drains; right?
A. Right.
Q. You looked at the use of antimicrobial prophylaxis?
A. Right.
Q. You looked at whether -- at the timing of the first dose of the antimicrobial prophylaxis

relative to the skin incision; right?
A. Right.
Q. You looked at the total duration of the operation; right?
A. Right.
Q. You looked at the total duration of the use of the -- of the intraoperative limb tourniquet; right?
A. Right.
Q. You looked at preoperative shaving; right?
A. Right.
Q. You looked at the -- the identity of the surgeon; right?
A. Right.
Q. And you looked at the use of a continuous passive motor machine. During post- -- excuse me -- including starting day and duration; right?
A. Right.
Q. That's something that was used after the surgery was completed to get the patient -- to start rehabbing; right?
A. Correct.
Q. You looked at the duration of post-operative fever; right?
A. Right.

Q. You looked at duration of antimicrobial exposure or administration; right?
A. Correct.
Q. You looked at the -- the lag -- the time between the surgery and when there was documentation of a wound infection; right?
A. Correct.
Q. You looked at the wound culture results; right?
A. Right.
Q. And you looked at the time of the total knee arthroplasty procedure, the time period between the -- the procedure and the first re-operation; right?
A. Correct.
Q. Okay. You looked -- you gathered information on all those factors as part of your -- your investigation here; right?
A. Right. And virtually all of those were negative. And part of the reason for going in that depth and looking at all of those factors was -- as I said, Dr. Simmons had had a hunch of what was going on. And we knew that if he were correct and it end up being a surgeon-specific issue, that we'd better have a lot of information on potential

factors that that surgeon would then raise to say, "Oh, no, it's not me."
So we looked at, as you can see, a very wide variety of other factors, most of which ended up being not significant.
Q. So are you saying you had no basis for looking at those other factors?
MR. B. GORDON: Object to form.
THE WITNESS: No. I'm saying they are factors that are potential. Many of them we probably didn't need to look at. But they were to make sure that when this surgeon objected, we could point out all the things that we looked at that weren't different.
BY MR. C. GORDON:
Q. Every one of those things that we just went through that you looked at, there was at least some basis for thinking that it could potentially have an impact on the deep joint infection rate; right?
A. Correct.
Q. I mean, you didn't look at the color of the paint on the operating room walls; that wasn't a factor you considered.
A. I don't think we looked at that; correct.

Q. And you didn't -- you wouldn't have considered that because there's no basis for thinking that changing the color of the paint in an operating room would have any impact on deep joint infections; right?
A. Oh, I don't know. If Dr. Simmons had said, you know, we've had a problem with the leak in our operating room and we just had a -- you know, painter come in and paint all the rooms then we probably would have focused on that. But since nobody said that, we didn't.
Q. Right. I'm talking about something as innocuous as the change in color, not, you know, painter leaving supplies or whatever might occur. You didn't look at things that realistically couldn't/wouldn't have had any potential to impact the joint infection rates; right?
MR. B. GORDON: Object to form.
THE WITNESS: Well, we tried to focus our attention on both, again, going back to the literature, what the literature had said previously were potential sources and other sources that we thought in addition to that could be important.
BY MR. C. GORDON:
Q. Well, if the concern was the surgeon, you

could have just looked at and compared that surgeon's rate to the other surgeon's rates; right?
A. Oh, absolutely. Dr. Simmons had already done that. But they don't [sic] think that was going to be very convincing to the surgeon. And the surgeon would have brought up the color of the paint in the room and everything else you can think of.
Q. Well, certainly the surgeon would have been interested in the ASA score, his patients versus the other patients; right?
A. Probably, since most surgeons, that's one of their arguments is I'm operating on sicker patients than you are.
Q. And as it turned out, in this case that was really true; wasn't it?
MR. B. GORDON: Object to the form.
THE WITNESS: Well, at least in terms of ASA score greater/equal than 3.
BY MR. C. GORDON:
Q. Well, in terms of that surgeon's group of patients versus the other surgeon's group of patients, his patients were almost 4 times as likely to have an ASA score of 3 or higher; right?
A. Right. But the potential confounding variable there that I don't think we looked at was

that he may have been linked with a specific anesthesiologist who might score patients higher. And I don't know that we looked at that.

Q. Is that something you considered looking at at the time?

A. I -- what year is this? Nineteen --

MR. B. GORDON: Ninety.

THE WITNESS: 1990. I don't remember. But that would be something that potentially we'd look at.

BY MR. C. GORDON:

Q. Actually, in your paper don't you say that the personnel in the operating rooms in the two different hospitals were basically the same for the other surgeons and they stayed in their own hospitals. In other words, it was just the surgeon moving back and forth?

A. Right.

Q. So if there was one anesthesiologist who was scoring patients higher on their ASA ratings, that wouldn't have differentially impacted one surgeon going back and forth between the two hospitals?

A. Well, he might have might have had a favorite at both places.

THE REPORTER: "Might have had"?

THE WITNESS: His favorite at both places.

BY MR. C. GORDON:

Q. Okay. So --

A. Just a possibility.

Q. But at least at the time you didn't consider that either at all or any significant enough possibility to actually investigate it?

A. Correct.

Q. But all these other things that you did investigate -- and, by the way, you also spent time -- some time to interview operating staff about operating room procedures; right?

A. Correct.

Q. You took all this information and you did a whole series of statistical analyses to see if any one factor or any combination of factors could explain the high rate -- the high rate of knee infections during this period; right?

A. Right.

Q. And you used a series of multi-variable analyses; right?

A. Right.

Q. And that's a way of comparing a -- several different potential factors to see if one or more is

having an impact on something; right?

A. That's one way of doing it; yes.

Q. Well, you could have done -- as I said, when you were called in, you could have just looked at surgeon X's infection rate and compared it to everyone else and done a univariate analysis and said it's all surgeon X; right?

A. Right.

Q. But by doing it this way you identified a couple of other factors that were in play; right?

MR. B. GORDON: Object to form.

THE WITNESS: Right.

BY MR. C. GORDON:

Q. And one of those was the ASA score we've talked about; right?

A. Right.

Q. And the other factor that you identified was this passive motion thing; right?

A. The continuous motion.

Q. Continuous motion?

A. Passive motion.

Q. Continuous passive motion.

And the combination of those three factors you concluded was -- of the problem or accounted for the problem; right?

A. Correct.

Q. So what would have -- well, strike that.

You couldn't reach -- you couldn't get to that conclusion until you gathered all the information about all these other potential factors; right?

A. Well, you could have gotten that information if you could have predicted the future by just collecting data on those three factors and be done. It would be a lot simpler.

Q. Right. But coming in after the fact and trying to figure out why there was a higher -- why there was a seemingly high rate of knee surgeries going on at these two hospitals, even though you had a working hypothesis that it was a surgeon-specific issue, you looked at all these factors that you reasonably thought could have had some impact on the infection rates and you then did a whole series of statistical analyses to flesh it out and see, you know, is it live or is it Memorex; right?

MR. B. GORDON: Object to the form.

THE WITNESS: Well, certainly collected all the data and did a variety of statistical analyses on it, yes.

BY MR. C. GORDON:

Q. And it wasn't just the surgeon; right?
A. Well, it mostly was the surgeon. The surgeon was a problem. You take the surgeon away, and the other -- the infections go away. So it's the surgeon and the surgeon's technique that are really the critical element here. Sure, his patients might have been a little bit sicker than other patients. Might have had more co-morbid conditions. But the fact was he was the problem.
Q. Well, if he had -- if you had reduced his patient load of patients with ASA scores of 3 or higher by 75 percent, would he still have had that high an infection rate, based on your -- the analysis you did?
MR. B. GORDON: Objection --
THE WITNESS: Well, that's --
MR. B. GORDON: -- form; speculation.
THE WITNESS: Speculative that -- whether he would have that high a rate. But my guess, given what was going on, is he would have had a higher rate than others operating on the same types of patients.
BY MR. C. GORDON:
Q. You say on page 914 that before conclusion could be drawn regarding surgeon X, it was essential

to rule out the possibility that the combination of these factors -- we've gone through many of them -- might account for the increased surgical wound infection risk experienced by some of his patients; right?
A. Where is that?
Q. 914. On the left-hand side of the first paragraph of that page -- on that page. About 20 lines down.
A. Correct.
Q. And then you did a series of logistic regression analyses; right?
A. Right.
Q. And that enabled you to conclude, "The severity of illness and surgical technique were the primary determinants for total knee arthroplasty-associated wound infection"; right?
A. Right.
And, again, I think that -- you know, certainly one of the things that was always done -- and it didn't matter if it was a surgeon, a nurse, a circulating nurse, a scrub nurse, who it was in the operating room -- if an epidemiologic study was identifying an individual, we would go to the Nth degree doing additional studies to really document

and prove that that was the case. Because we knew it potentially would have a devastating impact on their career.
So the idea that we could come in and do surgeon X versus everybody else -- infection? Yes, no. Get a P value. Go to the hospital administration and say, "Surgeon X is a problem, fire him" -- we would never do. We would go to the Nth degree looking at everything that could potentially -- and even things that might not potentially -- be associated with infection to make sure we were as solid as possible.
And in this case there was also a large number of patients who were having surgery done. So the numbers are large enough that you can really do a multivariate analysis or a stratified analysis. Which you might not be able to do with smaller numbers.
Q. But you don't think 3M is entitled to that same consideration that the surgeon was; right?
MR. B. GORDON: Object to form. Argumentative.
THE WITNESS: Well, I'm not aware that there's a cluster like this at a hospital. If there is and 3M wants to send me there, then I'll be happy

to do exactly the same thing.
BY MR. C. GORDON:
Q. Let's go back to the McGovern paper. They did a univariate analysis. The only two things they -- the only factor that they considered in the univariate analysis was whether it was Bair Hugger or HotDog; right?
A. Well, they're doing a different type of study. They're not doing a study of a specific short-time outbreak investigation. And their hypothesis from the very beginning of the study was is the type of patient warming device associated with increased risk of infection. So from the very beginning they're doing a much more focused type of study than we did in this outbreak investigation.
MR. C. GORDON: I'm sorry. Could you read that back.
(Record read as follows:
"A. Well, they're doing a different type of study. They're not doing a study of a specific short-time outbreak investigation. And their hypothesis from the very beginning of the study was is the type of patient warming device associated with increased risk of infection. So from the very beginning they're

doing a much more focused type of study than we did in this outbreak investigation.")
BY MR. C. GORDON:
Q. I want to -- I'm sorry. There are several parts of that, so I needed to have it heard back.
You said that they were -- "they" being the McGovern group -- were not doing a specific short-term outbreak investigation. Is that -- did I hear that correctly?
A. They did not identify a -- cluster of infections, was not what led them to go and do an investigation like we had with outbreak in Tennessee.
Q. What do you --
A. Tennessee was we have a large cluster of infections. Why is that occurring?
Q. What -- I want to parse this apart. What do you mean by "short-term"?
A. Well, here in outbreak, most --
Q. In your paper, you mean.
A. Right. Most outbreaks are occurring over a relatively short period of time. They don't go on for, you know, three years or even a year.
Q. Your period was 47 months; right?
A. Well, over a long period of time. That's

not when all of those infections were occurring, though.
Q. So when -- what was the period of time that the infections were occurring?
A. I had cluster, but really it's over a -- about a year period of time. He was having them virtually over a month. So it wasn't we have one, you know, now and we have one then.
Q. Why didn't you just look at that one year then?
A. Oh, we potentially could have. But again, as I say, we were trying to be very -- very conservative.
Q. Okay. Now in the McGovern paper you said that the hypothesis was the patient warming device was impacting infection rates; right?
A. Or is there any difference in infection rates given two different types of warming devices?
Q. Wasn't the -- your hypothesis on the study you did in Tennessee that one particular surgeon was accounting for the -- the high rate of infections?
MR. B. GORDON: Objection. He didn't say that.
THE WITNESS: Well, to begin the process at that hospital in Tennessee was to show that the

rate of infection was higher than the past rate. I don't know that I've seen any -- certainly anything reported in the McGovern paper that they had done that kind of analysis. It really was kind of a combination of change in use of a warming device around the same time that the Health Protection Authority mandated surveillance for prosthetic joint infections in certain patient populations. So it was kind of a combination of factors. But it was not -- I don't recall them saying we had elevated prosthetic joint infection rate, therefore we did this study.
BY MR. C. GORDON:
Q. Is it your understanding that the switch from HotDog to Bair Hugger -- from -- excuse me -- from Bair Hugger to HotDog in the McGovern paper occurred around the time that the HPA started mandating surveillance?
A. No. No. Beginning of the intensive surveillances was when the Bair Hugger was being used and that's the start of when -- that's kind of when they said we started collectings our data, is when the Health Protection Authority mandated going from doing surveillance on one of four procedures three months of the year to doing intensive

surveillance on basically a continuous basis. And that's when they hired the additional, I would call, infection control personnel. They call them surveillance personnel.
Q. When you went into the situation in Tennessee as is reflected in Exhibit 21, you were already aware that there had been a univariate analysis done of surgeon X versus everyone else, and that showed that surgeon X had a statistically significant higher rate of infections than the other surgeons; right?
A. Well, I don't remember if we had that or not. I know Brian Simmons had done some investigation before we got there and had a strong concern that surgeon X was problematic.
Q. So your working hypothesis when you went in there was that surgeon X was likely to be a factor; right?
MR. B. GORDON: Objection to form. Misstates his testimony.
THE WITNESS: Well, we went in with an open mind to say okay, you have an increased rate of infection. Let's see what the cause is.
BY MR. C. GORDON:
Q. So in the McGovern paper, are you saying

they didn't go in with an open mind?
MR. B. GORDON: Objection to form. Mischaracterizes his testimony.
THE WITNESS: No, I'm not saying they didn't go in with an open mind. I'm saying that our impetus in the outbreak was that there was an outbreak. There was an elevated rate of infection. I -- theirs was a specific hypothesis. Does the type of warmer that we're using in patients in the operating room have different rates of infection.
BY MR. C. GORDON:
Q. Well, there were different rates of infection in one time period versus another; right?
A. Correct.
Q. And their hypothesis was that the difference was because they had switched warming devices; right?
A. Well, they did that comparison. That's what they ultimately did their comparison of.
Q. And they didn't consider any of the other factors that you considered in your Tennessee study; right?
MR. B. GORDON: Objection to form. Asked and answered.
BY MR. C. GORDON:

Q. Not one.
A. Actually, I don't think that's true. They did look at some patient demographics that they had available to them and said there were no differences.
Q. What demographics?
A. I think it was during the deposition that they talked about it. I don't know that they talked about it here. Let me see.
Yeah. "The demographics of the 1437 patients undergoing hip and knee replacement revealed no significant difference between the two types of warming for SSI risk factors for age, type of surgery, diabetes, and length of preoperative stay."
Q. Okay. Sorry. Age, type of surgery, diabetes? What was the? Length --
A. Age, type of surgery, diabetes, and length of preoperative stay.
Q. Okay. They didn't do anything akin to -- on ASA preoperative physical status evaluation; right?
A. No. They said that wasn't available.
Q. Right. And when you did your study, that was -- that was a major factor?

A. Well, it ended up being a statistically significant factor. But if it hadn't been available, we wouldn't have been able to do it.
Q. You said that their study was much more focused; meaning, the McGovern study. What do you mean it was much more focused?
A. Well, they were looking at -- at least my understanding is they were looking at a -- trying to answer a specific question. Is there a difference in infection rate with two different patient warming devices.
So they're asking a specific question and collecting data to try to answer that question rather than, well, we have an outbreak. We have an increase in infection. Of all the different things that can be causing that, what is causing it.
Q. So if they had looked at all these other factors in both time periods and seen that, gee, there actually was a difference in one or more of these factors between the time period not just the patient warming, that could have impacted the conclusions they drew; right?
MR. B. GORDON: Object to form.
THE WITNESS: Well, you would certainly have to look at what they find and see does it make

any sense. It might have been -- going back to your color of the room. It might have been the color of the room. The blue room is where the infections are occurring. Well, it may not make any sense. So you have to look at anything that you find that is statistically significant.
BY MR. C. GORDON:
Q. But first you have to look; right?
A. If you have the data.
Q. Okay. And so when you say it's much more focused, what you're really saying is it was set up to only look at certain things; right?
MR. B. GORDON: Object to counsel's characterization.
THE WITNESS: No, I'd say they had a specific hypothesis that they were trying to answer and they collected the data and analyzed it that they thought was pertinent to that specific question.
BY MR. C. GORDON:
Q. And you collected data that you thought was pertinent to the Tennessee situation; right?
A. Well, I'd say we collected much more than that. If that had not been an individual surgeon, we would not have collected that much information.

Q. So tell me what you would -- what you would have eliminated if they had just called in and said, "Hey, our knee rates seem off the charts here; help us out." What you would you look at?

A. Well, it would be driven by a line listing. It would be driven by the past literature and what risk factors there were. Each investigation is individualized to that specific issue.

Q. Yeah, but --

A. But we would not have probably focused as much depth on certain factors in this outbreak if it had not been from the very beginning highly likely that the surgeon was going to be the cause.

Q. So I'm -- but my question is if you -- if the hospital had contacted the CDC and said, "Our knee rates are way higher than our hip rates and they're out of whack from what we understand to be the background rate at other places too, could you come and help us," what would you have looked at?

MR. B. GORDON: Objection; asked and answered.

THE WITNESS: Yeah, it would -- it would vary again depending upon the situation. But -- you know, presence of diabetes versus use of insulin.

You know, probably one of those would be -- diabetes is probably fine. Which is what they did. They didn't look at insulin. But probably don't need to.

MR. C. GORDON: Okay.

THE WITNESS: So the cause of the underlying disease. Probably not important. So -- you know, evidence of nosocomial infections.

So there's a lot of things that we're looking at that were overkill, but the reason that they were done was because we knew the probable outcome was going to be a very serious matter, that we needed to make sure we covered the potential -- any and all potential confounding variables that might exist.

MR. B. GORDON: Are we getting close to a good time for a break?

MR. C. GORDON: Yeah. One more question.

Q. Do you think these lawsuits are very serious matters?

MR. B. GORDON: Objection; argumentative. You don't have to answer that.

THE WITNESS: Oh, absolutely.

MR. C. GORDON: We can take a break.

THE VIDEOGRAPHER: The time is 3:37 p.m. and we are off the record.

(Recess taken from 3:37 p.m. to 3:51 p.m.)

THE VIDEOGRAPHER: This marks the beginning of Volume I, file 5 in the deposition of Dr. William Jarvis. The time is 3:50 p.m. and we are on the record.

BY MR. C. GORDON:

Q. Dr. Jarvis, several times today you made reference to a heater-cooler unit and you discuss that in your report, your expert report; correct?

A. Yes, sir.

MR. C. GORDON: And I show you Exhibit 22.

(Exhibit 22 marked.)

BY MR. C. GORDON:

Q. This is the Sommerstein June 2016 paper. This is something you reference in your report; correct?

A. Yes.

Q. And this discusses an investigation into an outbreak investigation of an unusual or relatively rare bacterium -- Mycobacterium chimaera?

A. Chimaera. Chimaera.

Q. Openly they link to contaminated heater-cooler units; right?

A. Correct.

Q. And in your report you describe the Bair

Hugger as being very, very similar to the heater-cooler unit; right?

A. Well, I described the -- it was broader than that. It was more that the heater-cooler is an example of a medical device that's been used in cardiac surgery for literally decades that everyone had assumed was safe and initially two patients were reported in the literature -- peer-reviewed literature that had this Mycobacterium chimaera infection after cardiac surgery and they were -- literally had their surgery two years apart.

And they're written up as a case report. And I thought it was interesting that the -- basically the last line in the abstract was, "No nosocomial source was found." And it's published. And it really was Sommerstein and colleagues in Switzerland who read that and decided to go back and look at their microdata to see if they had any cardiac surgery patients with mycobacterium chimaera and found they did that led them to do this study.

And by doing this study, they did the type of investigation that we have done at CDC, which identified the heater-cooler as the most likely source. And in culturing the device, as well as the air exhausted from this device, found that it was

releasing mycobacterium chimaera.

Since then a wide variety of others, including the United States and around the world, have found additional cases. Investigations done at the manufacturing plant of one of the manufacturers of this device Sorin, found that they -- some of the devices had intrinsic contamination at the time of manufacture. Some of them were extrinsically contaminated after manufacture. And that even though this has water in it, which is obviously different than the Bair Hugger, that it's really not water that's being aerosolized, it's the exhaust, air, similar to the contaminated exhaust air that's released from the Bair Hugger that has led to contamination of the sterile surgical field and surgical site infections.

And, in fact, since then a wide variety of other organisms have been reported to the Food and Drug Administration. So it's not just mycobacterium chimaera. And other manufacturers of the devices have been implicated as well. So it's an example of a medical device that everyone thought was safe for decades that now we know is not safe.

Q. Move to strike as nonresponsive.

Doctor, did you or did you not say on page

23 of your expert report, quote, "The Bair Hugger FAWs are very, very similar to the HCUs"?

A. Yes.

Q. You didn't just use one "very." You said "very, very similar to the HCUs"?

A. Yes.

Q. You really wanted to emphasize that similarity; right?

A. They're very, very similar; right.

Q. Let's take a look at the Sonner- -- Sommerstein paper, Exhibit 22. Page 1010 of that, if you would. Starting at the bottom of the paragraph on the left-hand side. It says, "The smoke reached the ultraclean airflow 0.5 meters beneath the ceiling outlet after 13 seconds, which resulted in a calculated mean airflow velocity of .23 meters per second. The smoke then reached the surgical field 10 seconds later, which resulted in a calculated mean velocity of 0.15 meters per seconds."

Did I read that correctly?

A. I'm trying to find where you're reading. It's on 1010?

Q. Yup. Under "Results."

"Smoke dispersal experiments in a

functional operating room." Starting with the very last sentence on the left-hand column. "The smoke reached the ultraclean airflow."

A. Okay.

Q. Okay.

A. Yes.

Q. So they give two figures for their calculated mean airflow: .23 meters per second and 0.15 meters per second. Do you see those?

A. I do.

Q. What's the mean airflow of the Bair Hugger?

A. In its exhaust?

Q. Yes.

A. I don't know.

Q. Do you have any order of magnitude comparison between the mean airflow velocity of the Bair Hugger and -- strike that.

Do you have any -- you may not have a quantitative -- strike that.

You may not have a -- it's late in the day. Strike that.

You may not have a quantitative number for the calculated mean airflow velocity but do you have a qualitative opinion as to whether the mean airflow

velocity of what comes out of the Bair Hugger is anywhere near close to either of those figures reported in Sommerstein?

A. No, I don't. But I don't think it's really relevant. Because, as you can see, the Bair Hugger is -- or excuse me -- the heater-cooler unit is in the corner of the room way away from the operating room; whereas, the Bair Hugger is usually located right at the side of the anesthesiologist near the operating room table. And I think 3M acknowledges that the air from the Bair Hugger is going into the blanket that's on top of the patient.

So we're talking about a device that's releasing its air right next to the patient versus one that's releasing air -- I don't care how fast or how slow -- way across the room.

Q. So whether the mean airflow velocity of the heater-cooler unit is sufficient to overcome the downward force of the ultraclean airflow from the ceiling, that, in your opinion, is irrelevant?

MR. B. GORDON: Objection. That's not what he said.

THE WITNESS: Well, I'm not saying that. It's obviously not irrelevant since patients are getting infected. But what I'm trying to emphasize

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is that I think it's even a greater risk with the Bair Hugger when it's releasing its contaminated exhaust directly either onto the patient or under the operating room table. If you move this device right underneath the table, it would be even greater danger than it already is.

BY MR. C. GORDON:

Q. In your report in several places you refer to the contaminated exhaust from the Bair Hugger. What's your evidence that the -- what comes out of the Bair Hugger blanket is actually contaminated with pathogens?

A. I think there's a number of studies that have been done. We talked about some of them this morning. But there's --

Q. Tell me what you contend supports your opinion that actual viable pathogens are being emitted from the Bair Hugger blanket?

A. Well, the studies that have been done I obviously refer to in the paper, but -- or in the report, but the studies documenting contamination of the Bair Hugger unit include Baker, Bernardo, Leaper. From 2009 Leaper; from 2001, Reed.

Q. Let me be precise with my question, Doctor, because I know you want to go off and talk

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about particles. I'm not asking about particles. I'm asking about viable bacteria. Do you have any evidence, any study you can point to that shows there are actual viable bacteria being emitted from the blanket of the Bair Hugger when it is in operation?

A. All of these studies that I'm referring to here have documented contamination of either the air coming in, the filter, past the filter, or the exhaust of the Bair Hugger unit. And we know from the Tsai study that soot can make it through that blanket to the patient. And, if so, a number of other studies have shown that bacteria, including Staph aureus, can get through a .22 or a .45 micron filter. And that the Bair Hugger blanket would not be a sufficient secondary filter, if you will.

Q. Move to strike as nonresponsive.

Doctor, does any study that you have seen demonstrate that actual bacteria have been measured coming out of the Bair Hugger blanket?

MR. B. GORDON: Objection to Counsel's tone and scowl.

He's answered the best he can.

THE WITNESS: Well, the majority of studies that have been done have focused on the air

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coming out of the hose; documented that the air coming out of the hose is contaminated.

BY MR. C. GORDON:

Q. Can you identify a single study that showed bacteria coming out of the blanket; yes or no?

MR. B. GORDON: Objection; asked and answered.

THE WITNESS: I believe --

MR. B. GORDON: He doesn't have to answer yes or no.

(Reporter asks for repetition.)

MR. B. GORDON: He doesn't have to answer yes or no.

THE WITNESS: Most of the studies as I mentioned have focused on the air coming out of the hose which is --

BY MR. C. GORDON:

Q. I'm not asking you about --

A. -- contaminated --

MR. B. GORDON: Objection. You're interrupting the witness.

BY MR. C. GORDON:

Q. I'm not asking you for most of the studies and what they focused on. I'm asking you if there

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are any studies --

MR. B. GORDON: Corey --

BY MR. C. GORDON:

Q. -- anywhere that you're aware of that have measured bacteria coming out of the Bair Hugger blanket.

MR. B. GORDON: Corey, I know you're getting excited, but you're going to let him finish his answer.

MR. C. GORDON: No, at this point it's filibuster.

MR. B. GORDON: And I object to interrupting the witness. Let him finish.

THE WITNESS: No. As I said, they focused primarily on the air coming out of the hose that has been documented repeatedly to be contaminated. And the Tsai study shows that the blanket would not serve as a secondary filter.

BY MR. C. GORDON:

Q. So you have no study that shows bacteria coming out of the blanket itself?

MR. B. GORDON: Objection; asked and answered.

BY MR. C. GORDON:

Q. Right?

A. No. As I said, they've -- the studies have focused on the intake, the machine, and the hose, air coming out of it.
BY MR. C. GORDON:
Q. Have you seen any studies that have actually focused on what was going coming out of the blanket?
MR. B. GORDON: Has 3M done?
THE WITNESS: I believe there's only -- I'm thinking there's only one very small study that used agar plates that attempted to look at that.
BY MR. C. GORDON:
Q. What did it find?
A. In that study -- as I say, it's a very limited study and they didn't find any.
Q. Are you aware of any studies that have attempted to find bacteria -- well, strike that.
In one of your answers there I think you said that there have been -- words to the effect of several studies that have shown contaminated air coming out of the hose. Is that essentially what you were saying?
A. Correct.
Q. What studies --
A. And in swabs of the hose as well.

Q. I'm not asking about swabs. I'm talking about what's airborne. Are you aware of any studies that have shown airborne bacteria coming out of the hose?
A. I believe there is.
Avidan.
(Reporter asks for repetition.)
Avidan, A-V-I-D-A-N, in their first experiment looked at nine Bair Huggers and one WarmTouch. Had the hose nozzle suspended 40 centimeters over agar plates. And three of the nine were positive.
Q. When you say "positive," how many CFUs were counted on the agar plates?
A. They were using agar plates. So I don't know that they quantitated them.
So they say in experiment 1, "Results. Microbes present in the airstream of warmers (Bair Hugger) grew corynebacterium" --
(Reporter asks for repetition.)
C-O-R-Y-N-E-B-A-C-T-E-R-I-U-M.
Another they grew staphylococcus.
Xylosus, X-Y-L-O-S-U-S. And aspergillus fumigatus. F-U-M-I-G-A-T-U-S.
And another they grew Cryptococcus,

C-R-Y-P-T-O-C-O-C-C-U-S.
Albidus, A-L-B-I-D-U-S.
And Aspergillus fumigatus. And staphylococcus xylosus.
Those were all from air streams, not from the hose.
Q. How many CFUs?
A. They did not quantitate it.
Q. And you said it was 40 centimeters off the agar plate?
A. Correct.
Q. That's about 16 inches; right?
A. Right. So a lot closer than the heater-cooler unit would have been to the operating room table.
Q. Right. The air in between the end of the hose and the agar plate, that's 16 inches or so of air. Was that sterile air?
A. No. The only thing they grew was aspergillus fumigatus.
Q. So were they -- did they do anything to determine whether what they were capturing on the agar plates 16 inches below the end of the nozzle was coming out of the nozzle as opposed to being blown onto the agar plate entrained from the

surrounding air in that 16 inches of space?
A. Nothing specifically, no.
Q. And that's the same study that you said once they put the blanket on and they put agar plates right under it, they got nothing; right?
A. Well, they -- in that case, in contrast to doing nine Bair Huggers, they just did two experiments. And the direct airstream was for five minutes.
Q. And they got nothing; right?
A. In those two experiments.
Q. Okay. And those were --
A. And they don't say how long the device had been on prior to the five minutes. And we know it takes, at least by other studies, 15, 20 minutes before it reached study state.
Q. And those two were two of the three that had bacteria, agar plates 16 inches below the airstream of the hose; right?
A. Correct.
Q. Are you aware of any studies that tried to measure the air directly coming out of the hose as opposed to having any kind of a gap in between?
A. No. I think the others did swabs, focused on swabs and/or actually taking liquid culture media

and putting that in the hose.

(Exhibit 23 marked.)

BY MR. C. GORDON:

Q. Let me show you what's been marked as Exhibit 23. Previously marked as Augustine Exhibit 8. Ask if you've ever seen this before.

A. Yes.

Q. When did you see it?

A. I couldn't tell you that. I don't remember.

Q. It's not listed on your references or your "Additional Materials Reviewed"; is it?

A. Yeah, I can't remember if I saw it as an exhibit. I may have. I don't remember.

Q. Well, I want to make sure we're talking about the same thing. There are several other exhibits to Albrecht that have that same "Augustine Biomedical & Design Research Report" thing at the top. But I will represent to you that this particular report was only marked as an exhibit in the Augustine deposition. So --

A. So I may not have seen it.

Q. Okay.

A. I may have just seen this front page. It looks very similar to something I have.

Q. Okay. So were you aware prior to this moment that Augustine Biomedical had done some experiments where they tried to capture any bacteria that might have been coming out directly from the air -- air hose?

MR. B. GORDON: Object --

BY MR. C. GORDON:

Q. -- the hose?

MR. B. GORDON: -- to the form. Lack of foundation. I don't know if he's even had time to even read this. If you want him to read the whole thing, it's a 29-page document.

BY MR. C. GORDON:

Q. You don't have to read this. I'm just asking you. As you sit here -- before you -- ignoring this. Did you have any knowledge that Augustine Biomedical had done any internal testing to try and capture bacteria that was coming out of the very end of the Bair Hugger hose?

MR. B. GORDON: Objection to form. Lack of foundation.

THE WITNESS: Yeah, I can't speak specifically to Augustine. I kind of vaguely remember that it might be Albrecht's deposition that something was mentioned about that.

BY MR. C. GORDON:

Q. Do you remember what Albrecht said in his deposition about that?

A. As I recall, he said that they were basically testing a variety of different methods to basically see what would work.

Q. And they couldn't capture any bugs using any of the methods; right?

MR. B. GORDON: Objection to counsel's characterization.

THE WITNESS: Well, or the methods that they used for the times that they -- you know, duration of the times that they used it, they hadn't detected it. But that they were just kind of just -- it was more just experimentation trying to figure out what method would be the best to try.

MR. C. GORDON: Let's go back to the HCUs.

(Exhibit 24 marked.)

BY MR. C. GORDON:

Q. Let me show you what's been marked Exhibit 24. These are record of proceedings from the HICPAC meeting December 1 through 2, 2016.

Have you seen this before today?

A. I believe I've seen sections. I think I've been online or I've looked at parts of it.

Haven't read the whole thing.

Q. It's not listed in your references or your "Additional Materials Considered [sic]"; is it?

A. I guess I would have included it as a CDC update. But the date's different.

Q. Well, if you --

A. Basically I've gone to the FDA and CDC websites repeatedly. And I go there to see if they've updated things. I don't put it -- write down every date that I go there.

Q. Well, do you recall -- but you don't recall seeing the December 1 and 2, 2016 meeting record?

A. I'd have to see what they say.

Q. Well, let's --

A. As I say, I might have read parts of this. I certainly have not read all of this.

Q. Let's turn to page 46.

MR. ASSAAD: What exhibit is this?

MR. C. GORDON: 24.

MR. B. GORDON: What was 23?

MR. ASSAAD: What was it?

MR. C. GORDON: I think it --

MR. B. GORDON: Oh, yeah. Did you mark that one 23?

MR. C. GORDON: I think it was this one.
MR. B. GORDON: Okay.
BY MR. C. GORDON:
Q. Have you made it to page 46 yet?
A. Yes.
Q. And there's a -- this is a -- essentially minutes of a presentation given by Dr. Michael Bell, the deputy director for the Division of Healthcare Quality Promotion, of the CDC; right?
A. Correct.
Q. Do you know Dr. Bell?
A. I do.
Q. In fact, it's Dr. Bell you've quoted in your report that -- words to the effect of nothing that blows air should be in an operating room; right?
A. Correct.
Q. And by -- you understood Dr. Bell to be referring to any piece of equipment that blows air. Is that -- that was your understanding?
A. Correct.
Q. So that would include computers that have little fans with CPUs in them; right?
A. Well, he didn't give an exhaustive list of what he meant.

Q. Did he give any list?
A. Well, he was talking about heater-cooler units. But he didn't -- no, he did not give an exhaustive list.
Q. Dr. Bell doesn't speak for the CDC; does he?
A. I don't know how you define that. He's deputy director of the division. So when he's speaking at a meeting like this, he certainly is speaking for CDC.
Q. Okay. So if he says this is the way it is, that is a pronouncement -- an official pronouncement of the Centers for Disease Control; is that what you're saying?
MR. B. GORDON: Objection to form. Argumentative.
THE WITNESS: Well, I guess that you would have to ask the director of CDC that question because it probably varies by the director and who's saying it and what they're saying.
BY MR. C. GORDON:
Q. Well, in your experience does -- somebody who is a deputy director of a division, do they have the authority to speak as -- for the CDC? Without any vetting, without any review, without any

oversight?
A. I wouldn't agree with that.
Q. Okay. So is it a -- as far as you know, is there a process within the CDC whereby for something to become an official position of the CDC there's some process that has to be undertaken?
A. I'd say there's numerous processes. For instance, if you look at -- in a CDC publication, there's a very specific process that you go through to get clearance of a paper that you publish at CDC. And yet at the bottom of the paper there's usually a disclaimer that it doesn't repre- -- necessarily represent the views of CDC.
Q. Okay. Is it your understanding as you sit here today that it's the official position of the Centers for Disease Control that no equipment that blows air should be in an operating room?
A. Well, again, I can't speak for CDC. So I'd be speculating. Certainly Dr. Michael Bell has said that. And I presume Dr. Denise Cardo, that's his boss who would have reviewed this, agrees with that. I can't tell you how far up the chain of command it would have gone.
Q. Well, let's see what Dr. Bell says in Exhibit 24, which you have in front of you.

Do you see where Dr. Bell at the very bottom of page 46 says that -- it says that Dr. Bell shared this draft device selection algorithm with HICPAC --
A. Yes.
Q. -- do you see that?
Okay. And then on the next page there's a device selection algorithm. Don't worry. I'm not going to try and make you read that.
A. Thank you.
Q. But do you have any idea, first of all, what -- what the word "draft" means in this context?
A. I'm assuming that it means that he's put this together and he's sharing it with HICPAC to get their comments and suggestions and it's not final yet.
Q. That would be a normal process; wouldn't it?
A. Well, it is a process, yes.
Q. And the statement that you've quoted about "nothing that blows air should be in an operating room," that pre-dated this; didn't it?
A. Yes.
Q. And it was in the context of a HICPAC discussion about how to deal with the heater-cooler

situation; right?
A. And Dr. Bell's assessment of other equipment that has blowing air in the operating room. I don't think he was being specific only to heater-coolers or he would have said no heater/cooler device should be in an operating room.
(Exhibit 25 marked.)
BY MR. C. GORDON:
Q. Okay. Well, I'm going to give -- show you Exhibit 25. And I will represent to you that this is a readable version of the device selection algorithm that appears on page 47. And if you follow that algorithm through, the algorithm starts with a product X. And first question is, is it reusable, yes or no.
Bair Huggers are reusable; right?
A. Correct.
Q. So you go over to the yes side. And then is it used in a patient care area? High risk, non-risk, or no-patient exposure.
We'll put the Bair Hugger in a high-risk area; right?
A. I would.
Q. Okay. Then the next line down to the left is "Is there" -- the box is "air/water interface."

Do you see that?
A. Yes.
Q. Okay. And by the way, if you -- the text on page 47 specifically says the high-risk box includes consideration of the air/water interface through processing issues," et cetera, et cetera.
Now, under "air/water interfaced" -- under "air/water interface," the second box over from the left is "uses fan"; right?
A. Correct.
Q. But under this algorithm you don't get to whether it uses a fan or not unless there's an air/water interface; correct?
MR. B. GORDON: Objection to counsel's characterization of the document and his testimony about what this means.
Also refer you to this paragraph for a moment.
THE WITNESS: I'm sorry?
MR. B. GORDON: That's what he referred you to there, the bottom of there.
THE WITNESS: Is there a question?
MR. C. GORDON: Yup.
Could you read it back, please.
(Record read as follows:

"Q. But under this algorithm you don't get to whether it uses a fan or not unless there's an air/water interface; correct?")
THE WITNESS: It actually looks like when they're discussing it, that in fact that air/water interface is merely being reinterpreted more as air or water and not necessarily air/water interface. And there's a considerable amount of discussion by HICPAC members about adding a section regarding whether a device can be cleaned at all, which we know 3M has no recommendation for cleaning the hoses of the device.
BY MR. C. GORDON:
Q. Can you show me where there's this discussion where you contend it means -- shows that the air/water interface means air or water?
MR. B. GORDON: I'm going to object. He was in the middle of a sentence in explaining exactly that. So let him finish.
MR. C. GORDON: I want to -- he can come back and give a speech. I want to focus on the air/water interface issue, not the cleaning issue.
MR. B. GORDON: He's answering the question to the best of his ability in the context

of this document and what you showed him.
BY MR. C. GORDON:
Q. Where in --
MR. B. GORDON: You interpreted it one way. He's trying to give you his interpretation.
BY MR. C. GORDON:
Q. Right. Where in this document does it say that air/water interface really means air or water?
MR. B. GORDON: I object to interrupting the witness. Please let him finish his answer.
THE WITNESS: On page 47 at the bottom it says, "High-risk box includes consideration of air/water interface reprocessing issues and instructions. Under the air/water interface are items related to moisture, creates mist, uses fan, requires water, uses tubing, dry-ability, biofilm, resistance. These elements were included to stimulate thinking. First-cut elements were included to stimulate thinking about items that impact reprocessing, as well as" -- blah, blah, blah, blah, blah, blah, blah. And then they go on to talk about the importance of cleaning devices. "And the manufacturer should be providing better instructions for cleaning devices."
BY MR. C. GORDON:

Q. Is there --
A. It says, "Inclusion of air/water is laudable. Air and water should receive attention particularly after the experience with heater-cooler units when their emissions were not taken into account." That's page 48, fourth from the bottom paragraph.
They also talk about maintenance is important. Should be part of the criteria, which we know. The hoses in the Bair Hugger cannot be cleaned. There's no recommendation for that at all. It says, "Consideration should be given to the composition of the materials in the device such as tubing links." We know that can be a problem.
Q. Doctor, I'll let you come back and talk about cleaning all you want because I know that's the big -- that you want to. But is there anything else in here that talks about the air/water interface? And I want to specifically focus on your testimony from a few moments ago where you said you read something that said it's air or water.
MR. B. GORDON: Object to the form. And counsel's mischaracterizing his testimony; it's argumentative. It says "air/water." You interpret that one way. He's explained his interpretation.

THE WITNESS: And they talk about -- Dr. Bell says, "The algorithm is a collection of elements to be considered. Weighing a different element needing to be taken into consideration is likely to be challenging."
BY MR. C. GORDON:
Q. Is there anything in here that says that when it says air/water interface what that really means is air or water?
MR. B. GORDON: Object to the form. Argumentative. It doesn't say "air and water." It says "air/water."
THE WITNESS: (Witness reviews document.)
MR. B. GORDON: And it's asked and answered. He's referred you to that sentence on page 48.
THE WITNESS: Yeah, I would just say my last answer is what I would say. If you look at it -- he's asking for additional comments and suggestions. And my interpretation of that is air/water was could be air or water.
BY MR. C. GORDON:
Q. So you believe when they -- it says air and water should receive attention," that really means air or water?

MR. B. GORDON: Object to form. Argumentative.
THE WITNESS: Well, I think it means it could be air and water or and/or water. And they're talking about devices that need to be cleaned and they're talking about devices that have hoses.
BY MR. C. GORDON:
Q. What does the word "interface" mean to you?
A. Where two things interface.
Q. You have to have two things; right --
A. Right.
Q. -- not just one?
MR. B. GORDON: Objection to form.
THE WITNESS: It could be. That could be one interpretation. Again this is a draft. And he's asking for comments from other people in the room.
BY MR. C. GORDON:
Q. What would an air interface be?
A. For instance, where the hose from the Bair Hugger comes in contact with the blanket would be an interface. And we know they're talking about connections with hoses.
Q. I know. I'm talking about where it says

"air/water interface." You're saying that your interpretation of that is it means air or water interface. I'm asking what's an air interface?
MR. B. GORDON: Objection to form. Argumentative. Asked and answered.
THE WITNESS: Well, I -- and I just described one for you.
BY MR. C. GORDON:
Q. And you think that's what Dr. Bell is talking about and the HICPAC people are talking about, that it's any -- any air interface with anything I said?
MR. B. GORDON: Objection to form. Characterization of the record. And argumentative.
THE WITNESS: Well, they're talking about medical devices that are in the operating room.
THE REPORTER: They're talking about what?
THE WITNESS: Medical devices that are in the operating room.
BY MR. C. GORDON:
Q. Actually, Doctor, they're talking about devices where there's water and an interface with an -- with the air in such a way that the bacteria that could grow in the water could be aerosolized into the air --

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MR. B. GORDON: Objection. Counsel's testifying.
BY MR. C. GORDON:
Q. -- isn't it?
A. Well, that's one interpretation. That's yours. I don't see where Dr. Bell specifically says that, number one. And, number two, if it follows up on his previous statement that no device blowing air should be in the operating room, then obviously if he limits it only to air/water interface, then he's going to miss out on other potential dangerous devices.
Also, if you think about it, he's developed this or started the development of this and hopefully it will lead to further discussion because of the follow-up investigations that led to the discovery of heater/cooler units being a problem.
Obviously before that hadn't come up with this. So hopefully this will be expanded to address all of those other devices in the operating room that have exhaust.
Q. How much do you charge per hour for your expert work?
A. It varies depending on what I'm doing.

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Q. Tell me the different rates.
A. For review and materials, it's $700 an hour. For sitting here with you it's $800 an hour. And at trial it's $900 an hour.
Q. Is there a minimum fee for a deposition too?
A. Yes.
Q. What's that?
A. I got to look. I think it's four or five hours.
Q. And what percentage of your income in the last couple of years has come from your work as an expert witness in lawsuits?
A. I'd say probably 10, 15 percent.
Q. And what's the other 80 or 90 percent come from?
A. My other consulting work that I do.
Q. Well, what kind of consulting work do you do?
A. I consult in epidemiology, infectious disease, hospital epidemiology and infection control for medical device companies, for infection control organizations, for ministries of health, for hospitals or hospital systems, and occasionally for individual practicing clinicians.

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Q. Do you charge those -- all those entities the same thing?
A. Some more; some less.
Q. And what's your highest rate for consulting?
A. For a one-hour presentation, it's -- I think the highest I've charged is $5,000 or $7,500.
Q. Okay. And if you're doing some sort of ongoing work as opposed to a single presentation, do you go by the hour or by the project? Or how do you do that?
A. It varies. I've done both.
Q. Do you have a standard hourly rate when you're billing by the hour?
A. It's somewhat dependent upon what I'm doing.
Q. Give me the parameters, ranges.
A. If I'm having to deal with media, it's usually in the 8- or $900 an hour range. If I'm doing on-site outbreak investigation, it could be somewhere in the 500 to $700 an hour range.
Q. When was the last outbreak investigation you did in the United States?
A. Well, I get asked to do them not infrequently but I don't do them very often for the

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very reason you're talking about. They're very expensive.
Q. Who -- what type of organization asks you in the United States?
A. Hospitals.
Q. Is there any reason those hospitals couldn't go to the CDC and ask them to do investigation?
A. Well, they could go to CDC. But, realize, CDC is a -- first of all, it's a non-regulatory agency except for NIOSH. Second is in order to have CDC come and do an investigation takes a fair number of approvals. It has to be approved at the branch level. Then the division level. Then the center level. And then the -- actually the group that funds the people that go out and do the outbreak have to approve it. It has to be approved by the state health department.
So if there was an outbreak at San Francisco General and they called CDC and said, "We want you to come do an outbreak investigation." If the San Francisco Health Department and the California Health Department didn't concur with that, they would not be allowed to go do it.
And in addition to all that bureaucracy,

sometimes hospitals would like to keep it quiet. And if they have their own private consultant do it, they control the outcome. Whereas, if CDC comes, it's available under the Freedom of Information Act.

Q. You're a board certified pediatrician; correct?

A. Yes, sir.

Q. You are not board-certified in infectious diseases; are you?

A. Board-eligible but I've never taken the boards.

Q. Do you have board certification in infectious diseases?

A. No.

Q. Are you -- do you consider yourself an expert in orthopedic surgery?

A. In the actual performance of the surgery, no.

Q. Do you consider yourself an expert in computational fluid dynamics?

A. Definitely not.

Q. You described Dr. Elghobashi's CDC study as excellent. Page 23 of your report. Do you see that? Or do you recall that?

A. I don't recall it, but I can look and I

think it's probably true. 23?

Q. Yup.

A. So "excellent study," yes.

Q. By what criteria did you come to the conclusion that it was an excellent study?

A. By looking at the factors that he included in it and basically the robustness of the study. Certainly compared with Dr. -- I think it's -- Memarzadeh's letter to the editor.

Q. When did you read Memarzedah's letter to the editor?

A. I couldn't tell you. Certainly before I wrote my report; that's for sure.

Q. Did you seek to obtain any information about the underlying details of what Dr. Memarzedah did?

A. No, I figured if they were important, he would have put them in the letter to the editor.

Q. Did -- well, when you say Dr. Memarzedah did something, it was actually the National Institutes of Health that did it; wasn't it?

MR. B. GORDON: Object to counsel testifying.

THE WITNESS: Well, that's like saying Dr. Bell speaks for CDC. I don't know that even

letters to the editor at NIH go through a review process. It's certainly not peer-reviewed.

BY MR. C. GORDON:

Q. Okay. But in terms of who -- well, you understand -- strike that.

You understand that Dr. Elghobashi did his CFD at the request of plaintiffs' counsel in this litigation; right?

A. Correct.

Q. And he was paid by plaintiffs' counsel in this litigation for his CFD; right?

A. I would presume so.

Q. Whatever Dr. Memarzedah said he did, that was done through the National Institutes of Health; right?

MR. B. GORDON: Object -- object; counsel's misstating the facts.

THE WITNESS: Well, I have no idea if someone asked him to do that or he did it on his own or how it came about. I don't know -- he doesn't say anything in his letter to the editor about that so I don't know.

BY MR. C. GORDON:

Q. Did you ever -- you didn't ask plaintiff's counsel to provide you with any documents they might

have that would show you what Dr. Memarzedah actually did for his CFD, did you?

A. No. I figured if he had some information and thought it was useful, he would have actually written an actual peer-reviewed publication rather than a letter to the editor.

Q. Did you -- you read Dr. Samet's report; did you?

A. I did.

Q. You saw that he had cited in his list of reference materials Memarzedah documents that actually were the whole CFD?

A. What was the last part?

Q. Did you see in Dr. Samet's report where Dr. Samet had unpublished information about the actual CFD modeling that Dr. Memarzedah did?

A. I'd have to look back. I don't remember that.

Q. Okay. Do you remember discussing the Memarzedah CFD with Dr. Samet when you met with him?

A. No.

Q. How did you determine that Dr. Memarzedah's CFD was not only not excellent as Dr. Elghobashi's but was -- was unworthy of even mentioning in your report?

MR. B. GORDON: Object to the form. Argumentative.

THE WITNESS: Because, as I said, it's not a peer-reviewed publication. Letters -- as an editor of a journal I can tell you letters to the editor are not sent out for peer review. An editor looks at it and decides, yeah, okay or no, not.

If Mr. Memarzedah thought it was an important piece of work that he had done, I would have expected him to write a full paper, not a letter to the editor, that included his methods and his results and his interpretation and submit it for publication.

BY MR. C. GORDON:

Q. Was Dr. Elghobashi's study that you describe as excellent peer-reviewed?

A. Not yet. But I don't know that he's not writing it up for submission to publication. I have no idea.

Q. So explain to me why you were able to -- why you thought Dr. Elghobashi's non-peer-reviewed study commissioned by the plaintiffs was excellent, but Dr. Memarzedah's CFD didn't even merit a mention in your report?

MR. B. GORDON: Objection; asked and

answered.

THE WITNESS: Well, because there's very little in the way of methodology provided by Dr. Memarzedah; whereas, Dr. Elghobashi has page after page after page describing his methodology what he's included, what he's not included, how he's done it.

I have a much better understanding given my limited understanding of that area of the extent of work and the robust nature of his analysis, compared to the very minimal description by Dr. Memarzedah.

BY MR. C. GORDON:

Q. Have you ever seen a Bair Hugger in operation?

A. Yes.

Q. When?

A. Well, I've probably seen it when I spent time -- my -- part of my consulting work is going into orthopedic surgical suites and providing guidance on methods for reducing infections. So I've seen it in those conditions. And I've seen it outside the operating room as well.

Q. Have you specifically examined a Bair Hugger in connection with this litigation?

A. I don't know what you mean by specific. I've not --

Q. Set it up.

A. -- taken a screwdriver and torn it apart, no. But certainly in terms of turning it on, yes.

Q. Okay. When?

A. Within the last year. Not in the last month. Within the last year.

Q. Where was -- where did you do that?

A. In Minnesota.

Q. In a law office or in a hospital or somewhere else?

A. In an office. And actually they had it at Science Day as well.

Q. Fair enough.

A. I think 3M gave a demonstration then. Hopefully they knew what they were doing.

Q. Other than the demonstration that was done at Science Day, did you -- have you seen -- have you seen it set up and operating outside of an incidental encounter in a hospital?

A. I'm not sure what you're getting at. I've seen it in an operating room --

Q. I'm not saying --

A. -- and I've seen it in an office. I'm not

sure what you mean. Have I seen it in a grocery score? No.

Q. Now let's talk about the office. Where -- that was an office in Minnesota and separate from Science Day? That's what I want to make sure.

A. Correct.

Q. And was that before or after Science Day?

A. Before.

Q. And how was it set up? Was it -- was there a mock patient or a real patient? Was it -- was the -- blanket attached? Those sorts of things.

A. Blanket was attached. It was turned on.

Q. What type of blanket was it?

A. You mean what model number?

Q. Upper body. Lower body.

A. Upper body.

Q. Okay. And where was -- was there any draping on it?

A. No.

Q. Was it pointed down or pointed up?

A. Down. In terms of air circulation, down.

Q. Right. Was it just on a table or on a floor or -- where was it?

A. Both on a table and a floor.

Q. Okay. And what did you look at? What

were you looking at?
A. The whole thing.
Q. Did you do any measurements?
A. No.
Q. Did you put your hand under the airstream?
A. Yes.
Q. How long did you run it? Or whoever ran it? How long did it -- how long was it run?
A. I'd say somewhere in the range of 10 to 15 minutes.
Q. And did that inform your opinions in any way --
A. No.
Q. -- that experience?
A. No.
Q. If you could turn to page 8 of your report, Exhibit 1?
A. Page 8?
Q. Yup. In your -- the second full paragraph on the top of that page you say, "Data from the CDC's NHSN have demonstrated that surgical procedure-specific and surgeon-specific SSI rates are essential." Do you see that?
A. Yes.
Q. And you have no information about the

surgeon-specific rates in the McGovern study; right?
A. Correct. But I'm specifically there talking about surveillance data. The NHSN is a CDC national healthcare safety network that does nationwide surveillance of healthcare-associated infections, including surgical site infections and prosthetic joint infections. So it's talking specifically about if you're doing surveillance, those are very important.
Q. How big are the bacteria that cause peri-prosthetic joint infections?
A. Well, they vary depending upon the bacteria. But something like Staph aureus is in the range .4 to .8 microns.
Q. It's your understanding that there are Staph aureus bacteria that come as small as .4 microns?
A. Correct.
Q. And where -- do you have any -- anything you can cite to that would support that?
A. I could get them for you. Probably microbiology textbooks.
Q. Okay. Have you -- have you looked at a microbiology textbook any time recently to see if your recollection of what size a staphylococcus

bacterium is is correct?
A. I've looked at literature.
Q. Recently?
A. Yeah.
Q. Why?
A. So I'd know the answer to that question.
Q. And based on recent -- this recent literature review, you found support for the notion that an individual staphylococcus bacterium can be as small as .4 microns?
A. .4 to .8 microns.
Q. You've mentioned soot on a number of occasions; right?
A. Maybe twice.
Q. Okay. And you've mentioned it in your report; right?
A. Correct.
Q. How big is soot?
A. Probably varies.
Q. What's the range of a soot particle?
A. I'd have to look that up. I'm not sure offhand.
Q. Is it --
A. It can be -- it can be very similar to what we're talking about in terms of bugs. In that

the bacteria like Staphylococcus could be one single organism. It could be two, it could be 10, it could be 100, it could be on a skin squame, it could not be. So it's -- you know, it varies. And the same thing with soot. It could be one particle or it could be many particles in aggregate.
Q. Could a soot particle be smaller than an individual staphylococcus bacterium?
A. I don't know. I'd have to look it up.
Q. You didn't look it up before you concluded the fact that soot particles escaped the Bair Hugger blanket means that bacteria can escape a Bair Hugger blanket?
A. Repeat that question, please?
Q. Well, you didn't -- one of your -- one of the bases of your opinions is the poster at the MD Anderson center in Texas where water got into a Bair Hugger somehow or -- and shorted out the circuitry and an electrical fire or something ensued and soot came out of the blanket onto the patient; right?
A. It probably was on the floor, huh?
Q. The soot?
A. No. The Bair Hugger.
Q. No, I'm talking --
A. That's how it got water on it.

Q. Well, you -- do you know how it got water on it or in it?
A. I'm assuming it probably was on the floor.
Q. Okay. But it's just an assumption on your part?
A. Correct.
Q. Okay. But I'm talking about the soot that you -- you referred to in your report. You --
A. Okay.
Q. -- point to that as evidence that bacteria can get onto the blanket; right?
A. Correct.
Q. But you -- before you rendered that opinion, you didn't look to see if soot particles could be substantially smaller than bacteria, did you?
A. I didn't go look up particulates. Obviously the studies of particulates have looked at a variety of different sizes. So the smallest sizes that they've looked at is I believe about 3 mi- -- .3 microns. So it's somewhere in the range of Staph aureus. Plus we know from microbiologic studies that Staph aureus can make it through a .22 or .45 micron filter. So I suspect that the holes in the Bair Hugger are bigger than that.

Q. So your understanding is that a soot particle doesn't get any smaller than .3 microns? Is that what you're saying?
A. No. What I'm saying is that when they're doing their particulate studies, they look at a variety of different sizes, which I suspect soot can do as well. And that one of those sizes is about .3 microns. And my guess is it's -- some soot particles can be about that size.
Q. But it's just a guess on your part; you didn't do anything to look into that, did you?
A. I didn't. I mentioned that.
Q. So if soot particles could be as small as, say, .1 micron, then the fact that a bunch of .1 micron soot particles got out of a Bair Hugger blanket doesn't tell you anything about whether larger bacteria would or would not get out of that blanket, does it?
MR. B. GORDON: Objection to form. Lack of foundation. Calls for facts not in evidence.
THE WITNESS: Well, that assumes that they kind of line up individually and run through the blanket, they don't aggregate, and that none of them are larger sizes than that. And I don't know that that's true.

BY MR. C. GORDON:
Q. Fair enough. So I -- I was asking about individual, single -- a single bacterium. You're saying -- you're saying that bacteria actually tend to aggregate; right?
A. Well, I didn't say they tend to; I said they could.
Q. Well, is it typical for an individual bacterium to float around all by its lonesome?
A. Like I said, it depends on the bacterium you're talking about.
Q. I'm talking about --
A. Certainly Mycobacterium tuberculosis does that.
Q. I'm talking about the ones that cause peri-prosthetic joint infections, the prominent ones.
(Reporter asks for repetition.)
Let's talk about staphylococcus. Does staphylococcus -- do staphylococcus bacteria tend to cluster together, or do they float around as individuals?
A. Well, I don't know that anybody really knows the answer to that. But they probably more likely are on skin squames.

Q. How big is a skin squame?
A. Probably in the 5- to 10-micron range.
Q. A lot bigger than soot; right?
MR. B. GORDON: Objection to form --
THE WITNESS: It depends on --
MR. B. GORDON: -- assumes facts not in evidence.
THE WITNESS: It depends on if the soot is aggregated or not.
BY MR. C. GORDON:
Q. You have no idea how big the soot was that came out of the blanket at the MD Anderson center in Texas, do you?
A. I don't believe they provided any sizing.
Q. And they didn't provide any analysis whereby they were -- tried to extrapolate from the finding that soot came out to the question of whether bacteria could come out of the blanket, did they?
A. I don't remember if they speculated on that or not. I think it was more just a description of what happened and that it raised their concern that bacteria could come out. And that the allegation or hypothesis that the blanket was a secondary filter was not true.

Q. And when you talk about -- strike that.
When you talk about the soot coming out of the blanket, the MD Anderson situation, you used that as support for your conclusion that the Bair Hugger is capable of emitting bacteria, you're just speculating too; aren't you?
MR. B. GORDON: Objection to form.
THE WITNESS: I don't know that I'd call it speculation. I put that in the context of all the other materials that I reviewed in terms of bacteria size, in terms of particles being generated by the Bair Hugger machine.
You know, so the fact that soot has made it through the blanket, to me adds additional information to that, suggesting that if that contaminated air is blown into the blanket, that why is it going to be filtered any more than the soot would be --
BY MR. C. GORDON:
Q. Even though you --
A. -- and it wasn't.
Q. Even though you have no idea how big the soot particles were?
A. Well, I know the soot particles aren't giant. You were saying they might be smaller.

Maybe they are, maybe they're not.
Q. And if they're smaller, that could mean that particles that are significantly smaller than bacterium might be able to get through the blanket, but that doesn't necessarily mean that bacteria-sized particles can get through the blanket?
MR. B. GORDON: Objection; lack of foundation.
THE WITNESS: Well, and, again, that supposes that one little particle of soot is going through. And it seems like from the pictures that they showed there were more than aggregates. Aggregates are more pieces of particles than one. That they basically were the size of the hole.
BY MR. C. GORDON:
Q. You're talking about a picture that you saw, or did you actually see the soot?
A. No. Picture of the patient with the little dots.
Q. And you -- and it's your understanding that each dot represented a single soot particle?
MR. B. GORDON: He didn't say that. Objection to form.
THE WITNESS: No. It's exactly the

opposite of what I'm saying. That I think it illustrates that there's more than one particle coming through that blanket hole. And that it may well represent aggregated soot, in which case the size may be in fact larger than a bacteria.
BY MR. C. GORDON:
Q. You say "may be aggregated." So it may not be; right?
MR. B. GORDON: Objection to form.
THE WITNESS: Well, I think it probably is.
BY MR. C. GORDON:
Q. Based on what?
A. Based on the size of the dot.
Q. On page 16 of your report you -- in the third full paragraph down, middle of the paragraph where you talk about, "The previously mentioned studies have shown that" -- et cetera, et cetera, "Bair Hugger FAW exhausts bacterially contaminated air into the OR."
Do you see that sentence or that part of the sentence?
MR. B. GORDON: Page 13?
MR. C. GORDON: Page 16.
MR. B. GORDON: Sorry. Thank you.

BY MR. C. GORDON:
Q. It says "exhausts bacterially contaminated air into the OR." That part of the sentence that I want to talk about.
A. Correct.
Q. What study or studies have demonstrated that Bair Hugger exhausts bacterially contaminated air into the OR?
A. Well, I think it's a constellation of studies, number one. So it's studies showing through swabbing air cultures, even rinses of the hoses had bacteria that contaminated air is exiting the hose. Together with the example of the soot making it through the blanket showing it's not a secondary filter. Plus the numerous studies showing that the Bair Hugger increases particulates in the sterile field. So it's really a conglomeration of those.
MR. C. GORDON: Let's take a break. Nearing conclusion. I just want to go over my notes.
THE VIDEOGRAPHER: The time is 5:03 p.m. We're off the record.
(Recess taken from 5:03 p.m. to 5:16 p.m.)
THE VIDEOGRAPHER: This marks the

beginning of Volume I, file 6 in the deposition of Dr. William Jarvis. The time is 5:15 p.m. and we're on the record.

(Exhibit 26 marked.)

BY MR. C. GORDON:

Q. Dr. Jarvis, I'm going to show you what's been marked as Jarvis Exhibit 26. Is that what it --

A. Twenty- -- yeah.

Q. And it was previously marked as McGovern Exhibit 6.

I just want to ask if you've seen this before.

A. I don't think so.

Q. Do you recall reading Dr. -- strike that.

Dr. McGovern's deposition was one of those depositions that was not on your reference list -- strike that.

Dr. McGovern's deposition was not listed in your December 2016 billing. It hadn't occurred as of then. But it shows up on your "Additional Materials" list now. Do you know if you read McGovern's deposition before or after you rendered your opinion on March 31?

MR. B. GORDON: Objection. It was asked

and answered this morning.

MR. C. GORDON: I'm sure it was and I --

THE WITNESS: Yeah, I don't remember.

BY MR. C. GORDON:

Q. Okay. And when you read the McGovern deposition, do you remember reading any discussion of experiments that they attempted to do in Northumbria to simulate a surgical procedure and measure particles in bacteria using the Bair Hugger versus HotDog? Or just -- I think it was just Bair Hugger on or off.

A. So you're not talking about the bubble study at all?

Q. Not the bubble study. Completely separate study. Simulated surgery where they're measuring particles and bacteria.

A. Yeah, I don't remember.

Q. So in this particular study, where the results show, "The experiments showed no notable increase in either ambient particle count or bacterial count in the vicinity of an operative field when a forced air warming device was used in a normal intraoperative manner, there was an increase in local particle counts only when the surgeon enters the operative field from outside the laminar

flow boundary."

That's the first you've heard this, I take it?

A. Well, I'm thinking now, I'm wondering if this was part of an abstract that was submitted to a meeting that was not accepted and he was talking about negative results.

Q. Okay.

A. If that's the one, then, yes, I remember him describing it.

Q. And this is not -- you're right. There was an abstract. But this is not the abstract. This is the --

A. No, no, no. But I mean, I think that's the context that he was discussing it --

Q. Okay. So --

A. -- was that there was an abstract submitted to a UK orthopedic meeting and it hadn't been accepted.

Q. Did you con- -- well, strike that.

You didn't mention anything in your report about the attempt on the part of McGovern and Reed to count particles or bacteria in simulated operating room or simulated operation when the Bair Hugger was on; right?

A. Correct.

Q. You didn't think that was relevant or important to your opinions?

A. Well, I think the only thing I knew about it was what he said in his depo, which was pretty brief. Didn't go into detail about the methodology or the results.

Q. Did you ask to see the exhibits?

A. No.

(Exhibit 27 marked.)

BY MR. C. GORDON:

Q. Let me show you what's been marked as Exhibit 27. Previously marked -- collection here -- Augustine 60 and Gauthier 26.

You did not read the deposition of Dr. Gauthier; right?

A. No.

Q. Or Dr. Augustine; right?

A. Correct.

Q. So do you recall if you've seen this document before, couple of e-mails from July of 2010?

A. I don't think I've seen this, no.

MR. C. GORDON: I have nothing further. Thanks.

MR. B. GORDON: We've got about an hour. Do you want to take a break?

(Laughter.)

MR. B. GORDON: Actually, I think I might want to ask one little quick question.

MR. C. GORDON: Do you need to switch?

MR. B. GORDON: For seats?

MR. C. GORDON: Yeah.

MR. B. GORDON: No. Unless you want me to.

MR. C. GORDON: It's up to you.

EXAMINATION

BY MR. B. GORDON:

Q. Dr. Jarvis, you gave a lot of testimony this morning about the things that you did to frame or render your opinion as set forth in your report today. Do you recall that testimony?

A. Vaguely.

Q. Okay. I just want to have it clear for the record. Could you just take us through for the members of the court and the jury that may see this or read this, the scientific process that you followed in attempting to answer the question that you were looking at in this case concerning whether the Bair Hugger device was unreasonably dangerous or

not? And in that description include everything that you did, and not just the literature that you were questioned about, but everything and every part of the process that you followed in line with your CDC training.

MR. C. GORDON: Object to the form of the question.

THE WITNESS: Well, given my background and training in infectious disease and epidemiology and my time at CDC, being in charge of outbreak investigations, guideline development, and the surveillance system, using that knowledge and expertise to then try to evaluate all the different possibilities associated with the Bair Hugger.

So I did numerous Google and PubMed searches of a variety of different bacterial contamination of Bair Hugger units of was there data to associate Bair Huggers with increased particles in the sterile field. What is the impact of Bair Huggers on laminar airflow. What the Bair Hugger does in terms of airborne contamination and SSI risk. And the correlation between particles and microbes. So as many different combinations and permutations as I could of basically normothermia particles, airborne contamination.

I then reviewed the characteristics of the Bair Hugger device in terms of description on the internet, visualization of the product.

Then looked at the data on both published data as well as 3M data and data from a variety of depositions and exhibits. On how the Bair Hugger device was submitted for 510(k) with the description of having a high particulate air filter and how that was changed to MERV 14 filter. And then from the 500 series to the 700 series, downgraded to even less than that. How 3M had done studies specifically of the filter not in the device but in artificial laboratory setup showing its MERV 14 filter. But at least two studies done of the filter efficiency in vivo being closer to -- at least in the 700 series -- being closer to 60, 65 percent.

Looking at exhibits from 3M about their own concern about the efficacy of the filter and Project Ducky. And even though a variety of different methods including HEPA filtration were considered, none were implemented.

Looking at studies even from Sessler showing increase in in particulates associated with the Bair Hugger device and repeated requests from Dr. Sessler that 3M do a study comparing the Bair

Hugger with other warming devices.

Looking at the various depositions from Sessler, Kurz, as well as the others that have done these studies, particularly the McGovern study showing that -- neither McGovern nor Reed received any compensation for doing this study -- that they collected all of the data both from the bubble study as well as from the periods where the HotDog and Bair Hugger were used. And working with Albrecht to analyze that data and write the papers.

And to critically look at all of these different papers that addressed all of these different issues.

And really to me it's the comprehensive nature of all of that that leads me to believe that the Bair Hugger is a dangerous device and can cause surgical site infections, particularly in patients that have prosthetic joint implants.

Q. And to be clear on that, when you say surgical site infections in patients with prosthetic joint devices, you mean periprosthetic or deep joint infections?

A. Absolutely.

MR. C. GORDON: Objection; leading.

THE WITNESS: Absolutely.

BY MR. B. GORDON:
Q. And your opinions as you just stated and the documents you referenced, most of those are expressed in your report that you've issued in this case; is that right?
MR. C. GORDON: Same objection.
THE WITNESS: Right. And I certainly looked at, you know, like Dr. Elghobashi's work and looked at others as well in the literature. And -- so I've certainly looked at not only depositions but reports. I looked at and evaluated critically Dr. Samet, Dr. Elghobashi, and other reports.
BY MR. B. GORDON:
Q. And do you hold all these opinions to a reasonable degree of medical and scientific probability?
A. Yes.
Q. And have -- have you ever had an opinion -- an expert opinion be limited or excluded from consideration by a jury by any court in this land?
A. No.
MR. B. GORDON: Thank you, Doctor.
FURTHER EXAMINATION
BY MR. C. GORDON:

Q. You made reference to MERV 14.
A. Correct.
Q. What is that?
A. MERV 14 is an ASHRAE category filtration for devices. They have MERV categories ranging from 1 to used to be 20, but now it's to 17.
Q. You said it's a category for devices. Do you mean medical devices?
A. Well, it's -- no, it's specifically been recommended for ventilation systems.
Q. For hospital ventilation systems; right?
A. Well, that would be one of them, yes.
Q. Well, what -- what's a MERV 14 recommended for?
A. Recommended for operating rooms or higher. HEPA filtration, too.
Q. But as far as ASHRAE is concerned, the MERV 14 is adequate for an operating room?
A. For general --
Q. Let me finish.
-- ventilation system; right?
A. Well, they actually have two filters. So there's a pre-filter and then the MERV filter. So two filters are used. But the MERV filter has the highest filtration efficiency.

Q. And I think --
A. And it's for, as you say, general surgical operating room.
Q. And I think I heard you say that 3M downgraded the filter from MERV 14?
MR. B. GORDON: Objection; mischaracterizes his testimony.
BY MR. C. GORDON:
Q. And I don't mean to mischaracterize him. I may have misheard you.
A. Well, the initial 510(k) of the 500 series was supposed to be initially a HEPA filter, when the 510(k) was submitted according to 3M documents. And then it was changed. It looks like never told FDA that it was not a HEPA filter that was placed but, rather, a MERV 14 filter.
And that MERV 14 filter when tested outside -- so just taking the filter and putting it in a nice box where it's very tight and then challenging it, which 3M did twice -- basically met the criteria for a MERV 14 filter. But at least two investigators in peer-reviewed journals that did testing specifically of a filter from those devices, both a 500 series and a 700 series in use in a Bair Hugger, found that the filtration was much lower

than -- than that.
And from e-mail discussions with 3M personnel, it sounds like they were well aware that they, number one, didn't put a HEPA filter in and then, number two, that it might not even meet MERV 14 criteria.
Q. Is it your understanding that the filter in the Bair Hugger today is not MERV 14?
A. Well, all I can say is that testing of it in -- of an in-use device, device being used in a hospital, was, I believe, 63 percent or .3-micron challenge.
Q. And that was a study financed by Scott Augustine; right?
A. Well, I'd have to look back at the study. I don't know that he financed it or not. That doesn't change the result.
MR. C. GORDON: Nothing further.
MR. B. GORDON: Nothing further 'til trial.
THE VIDEOGRAPHER: This marks the end of Volume I, file 6 and concludes the deposition of Dr. William Jarvis. The time is 5:33 p.m. We're off the record.
(Discussion held off the record.)

MR. B. GORDON: So, Doctor, you have the right to read and sign your deposition. Would you like to exercise that right?

THE WITNESS: Yes.

(The proceeding adjourned at 5:35 p.m.)

_____

WILLIAM R. JARVIS, M.D.

Subscribed and sworn to before me this day of 2017.

CERTIFICATE

STATE OF CALIFORNIA)
: Ss
COUNTY OF CONTRA COSTA)

I, Heidi Belton, a Certified Shorthand Reporter, a Registered Professional Reporter, a Certified Realtime Reporter, California Certified Realtime Reporter, and Certified LiveNote Reporter within and for the State of California, do hereby certify:

That WILLIAM R. JARVIS, M.D., the witness whose deposition is herein before set forth, was duly sworn by me and that such deposition is a true record of the testimony given by such witness.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am in no way interested in the outcome of this matter.

In witness whereof, I have hereunto set my hand this 4th day of August, 2017.

_____

HEIDI BELTON, CSR, RPR, CRR, CCRR, CLR
Certified Shorthand Reporter No. 12885

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Signature of Deponent

SUBSCRIBED AND SWORN BEFORE ME

THIS ____ DAY OF _____, 2017.

_____

(Notary Public) MY COMMISSION EXPIRES:_____